[ORAL ARGUMENT NOT YET SCHEDULED]
Nos. 13-5011, 13-5015 (consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALLINA HEALTH SERVICES, *ET AL.*,

Plaintiffs-Appellees,

v.

KATHLEEN SEBELIUS, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant-Appellant.

On Appeal from the United States District Court
for the District of Columbia

BRIEF FOR APPELLEE

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties And Amici

All parties appearing before the district court and in this court are listed in the Brief for Appellant Kathleen Sebelius.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, the undersigned certifies that no Appellee has a parent company, and no publicly-held corporations have a 10 percent or greater ownership interest in any of the Appellees.

B. Ruling Under Review

References to the rulings at issue appear in the Brief for Appellant Kathleen Sebelius.

C. Related Cases

In Appellees' view, there are no related cases pending in this Court. There is one related case, involving the same defendant, some of the same plaintiffs, and related legal issues, pending in the District Court for the District of Columbia: *Palm Springs General Hospital, Inc. New Corp. v. Sebelius*, No. 13-648 (D.D.C.) (RMC).

/s/Stephanie A. Webster
Stephanie A. Webster

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES:

---

* Authorities upon which we chiefly rely are marked with an asterisk.

STATUTES AND REGULATIONS:

OTHER AUTHORITIES:

GLOSSARY

APA	Administrative Procedure Act
AR	Administrative Record
CMS	Centers for Medicare & Medicaid Services, formerly HCFA
DSH	Disproportionate Share Hospital
HCFA	Health Care Financing Administration, now CMS
Board	Provider Reimbursement Review Board (PRRB)
RR	Rulemaking Record
Secretary	Secretary of Health & Human Services
SSI	Supplemental Security Income
SAR	Second Administrative Record

ISSUES PRESENTED FOR REVIEW

Hospitals that provide a disproportionate share of care to low-income patients are entitled to Medicare payment for the increased costs of treating such patients, known as the Disproportionate Share Hospital ("DSH") adjustment. The statute requires the agency to count low-income patients differently depending on whether they were "entitled to benefits under part A" of Medicare for their patient days in a hospital. *See* 42 U.S.C. § 1395ww(d)(5)(F)(vi). This case involves the Secretary's treatment of days for patients who had elected to receive benefits under Medicare part C instead of part A. The questions presented are:

1. Whether the Secretary failed to give adequate notice and opportunity for comment prior to announcing she was revising her regulation to begin counting part C days as part A days, when the purported notice only clarified that her longstanding policy was not to count part C days as part A days and gave no indication that she was considering a policy change.

2. Whether the Secretary's announcement of an amended rule reversing her treatment of part C days is unreasonable when the Secretary did not acknowledge the reversal, the Secretary entirely failed to explain her rule change, and the Secretary did not and cannot explain how the new rule is consistent with congressional intent.

3. Whether a Medicare rule issued without adequate notice or opportunity for comment, and without any acknowledgement or explanation of the Secretary's policy reversal, must be vacated, and the previously-governing Medicare rule restored.

STATUTES AND REGULATIONS INVOLVED

Relevant statutory and regulatory provisions are attached in an addendum to this brief.

STATEMENT OF THE CASE

In 1986, the Secretary adopted a regulation implementing the DSH statute providing that only patient days covered by Medicare part A could be counted as days for which a patient is "entitled to benefits under part A." The agency did not change that rule when Medicare part C was enacted in 1997, so part C patient days were not counted as part A days.

In 2003, in response to questions from the industry, the agency issued a notice clarifying its policy under the regulation not to count part C days as part A days. In 2004, however, without any acknowledgment or notice that it was changing its longstanding rule and without any explanation, the Secretary tersely announced an amendment to the regulation to begin counting part C days as part A days. The agency did not immediately implement the change, however, failing to revise the actual text of the regulation until 2007, again without notice and

comment, and not publishing calculations reflecting the new rule until 2009, for fiscal year 2007.

The data the Secretary released in 2009 showed that the change would cost Appellees, thirty not-for-profit hospitals (the "Hospitals"), tens of millions of dollars per year. The Hospitals appealed and the Secretary's Board granted expedited judicial review. The district court held that the 2004 rule was adopted without adequate notice or opportunity for comment and that it was substantively invalid because the agency failed to acknowledge or explain the policy reversal. The district court therefore vacated the 2004 rule, reinstating the prior rule that counted only days paid by Medicare part A as part A days.

STATEMENT OF FACTS

A. Legal Framework

1. Medicare furnishes benefits to qualified individuals through different programs, organized under different parts of the Medicare statute.

Part A entitles an individual to have Medicare benefits paid by the Secretary, on the individual's behalf, directly to a "provider of services" for covered institutional services, including inpatient hospital services. *See* 42 U.S.C. §§ 426(c), 1395d(a)(1), 1395f(a)-(b), 1395x(u).

Part B is an optional program, requiring payment of premiums, that covers physician and certain other medical services that are not covered under part A. *See* 42 U.S.C. §§ 1395j – 1395w-4.

As amended by the Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275-327, part C establishes a managed care program as an alternative to the traditional fee-for-service programs under parts A and B.[1] *See* 42 U.S.C. § 1395w-21(a). Once an individual enrolls in a private part C managed care plan, he or she receives benefits under part C, and not under part A. *See Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6 (D.C. Cir. 2011). In order to enroll in the alternative part C program, however, an individual must have been entitled to part A and enrolled in part B. *Id*. at 2, 5; 42 U.S.C. §§ 1381-1383f.

2. Under the part A inpatient prospective payment system, Medicare pays hospitals predetermined per discharge rates for services to patients entitled to benefits under part A. *See* 42 U.S.C. §§ 1395f(b), 1395ww(d)(1)(A)-(B). Part A also provides for an additional payment to a "disproportionate share hospital," or "DSH," that treats a large proportion of low-income patients. 42 U.S.C. § 1395ww(d)(5)(F). Congress intended the payment to adjust part A payments to

[1] The part C program was originally called Medicare+Choice (or "M+C"); it is now called "Medicare Advantage." *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 201, 117 Stat. 2066, 2176.

compensate for the higher costs that safety net hospitals incur in treating part A patients. *See* Comprehensive Omnibus Budget Reconciliation Act of 1986, H.R. Rep. No. 99-241(I), at 15, *reprinted in* 1986 U.S.C.C.A.N. 579, 593-94.

3. The DSH payment calculation employs two measures, referred to herein as the Medicare "part A/SSI fraction" and the "Medicaid fraction," to approximate the proportion of low-income patients treated by a hospital. *Id.* § 1395ww(d)(5)(F)(vi). Both fractions consider whether a patient was entitled to benefits under part A:

Patient Days For A Hospital Cost Reporting Period	Part A/SSI Fraction	Medicaid Fraction
Numerator	"entitled to benefits under part A" and "entitled to supplemental security income benefits"	"eligible for [Medicaid]" and "*not* entitled to benefits under part A"
Denominator	"entitled to benefits under part A"	"total number of the hospital's patient days"

4. From 1986 through 2004, the Secretary interpreted the term "entitled to benefits under part A" in the DSH statute to mean covered, or paid, by Medicare part A. The regulation governing the part A/SSI fraction directed the Secretary to determine "the number of *covered* patient days that … [a]re furnished to patients who … were entitled to both Medicare Part A and SSI." 42 C.F.R. § 412.106(b)(2)(i) (2003) (emphasis added); *see* 42 C.F.R. § 409.3; *see also* 51 Fed. Reg. 16,772, 16,788 (May 6, 1986); 51 Fed. Reg. 31,454, 31,460-61 (Sept. 3,

1986); *Catholic Health Initiatives-Iowa Corp. v. Sebelius*, 718 F.3d 914, 2013 WL 2476896, at *6 n.5 (D.C. Cir. 2013); *Northeast Hosp.*, 657 F.3d at 14-17.

5. The agency calculates the part A/SSI fraction itself, for each federal fiscal year for every hospital in the country, using privacy-protected data that the agency obtains from the Social Security Administration. *Baystate Med. Ctr. v. Leavitt*, 545 F. Supp. 2d 20, 24 (D.D.C. 2008); 42 C.F.R. § 412.106(b)(2), (5). The agency's contractors determine the Medicaid fraction using hospital furnished data. 42 C.F.R. § 412.106(b)(4).

6. The agency did not change its interpretation of "entitled to benefits under part A" for purposes of the DSH calculation in 1997, when Congress enacted the part C program. Because the services furnished to part C patients were not covered and paid under part A, the agency did not count part C days in the part A/SSI fraction. *See Northeast Hosp.*, 657 F.3d at 14-17. Soon after Congress enacted the part C program, the Secretary instructed hospitals *not* to submit the billing information that the agency would have needed to count part C days in the part A/SSI fraction. *Id.* at 15.

7. In 2003, the agency indicated that it had received questions regarding the counting of part C days in the DSH calculation. The agency explained that "once a beneficiary has elected to join [a part C] plan, that beneficiary's benefits are no longer administered under Part A." 68 Fed. Reg. 27,154, 27,208 (May 19,

2003). The agency "propos[ed] to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare [part A/SSI] fraction of the DSH patient percentage," and should be included in the numerator of the Medicaid fraction, if Medicaid-eligible. *Id*. The Secretary did not propose any revision to the relevant portion of the text of the DSH regulation or solicit comments on this clarification. *See id.*

8. The Secretary received sparse comments on the 2003 clarification. Some comments reflected confusion and misunderstanding regarding the Secretary's own calculation of the part A/SSI fraction. Mistakenly believing that the Secretary had been including part C days in the part A/SSI fractions, they suggested that the agency maintain the status quo. *See, e.g.*, RR 343, 413, 466, 547; JA-.[2] Some comments recognized that the clarification merely restated what the agency was already doing. *See* RR 149, 390; JA-. As compared to the approximately 30,000 pages of comments received by the agency on a typical, annual part A payment system rule (in 2004), the agency received only 26 pages of comments on the 2003 clarification. *See* RR 144, 147-149, 343, 354, 370-371, 389-390, 412-413, 439, 449, 452, 466, 490, 513, 516, 546-547, 554, 556, 571, 576, 591; JA-.

[2] The rulemaking record is "RR," the administrative record in appeal 13-5011 is "AR," and the second administrative record in appeal 13-5015 is "SAR."

9. In the final 2004 rule, the Secretary "changed her interpretation of the DSH provision," *Northeast Hosp.*, 657 F.3d at 16, announcing that she was "adopting a policy" and "revising [the] regulation[]" to begin counting part C patient days in the part A/SSI fraction, 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). The Secretary's only explanation was that part C enrollees "are still, in some sense, entitled to benefits under Medicare [p]art A." *Id.* The Secretary claimed that this new policy would *not* have a significant impact on hospitals. *See id*. at 49,755, 49,770. In truth, the new rule reduces DSH payments to all hospitals nationwide by hundreds of millions of dollars per year. *See Northeast Hosp*., 657 F.3d at 5; *see also* PRRB Dec. No. 2010-D48 at 11, 13-14.[3]

10. The 2004 final rule stated that the agency revised its regulation. 69 Fed. Reg. at 49,099. The agency later said that it had "inadvertently" failed to change the regulation's text at that time and, in 2007, without notice or opportunity for comment, the Secretary amended the text of the DSH regulation "to conform" the text to the "policy change" the Secretary had first announced in the 2004 rulemaking. 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007). As amended, the regulation provided that the part A/SSI fraction includes all patient days for "patients entitled to Medicare Part A (or Medicare Advantage (Part C))." *Id.* at

[3] *Available at* https://www.cms.gov/PRRBReview/downloads/2010D48.pdf.

47,411 (amending § 412.106(b)(2)(i)(B) and (iii)(B)). The stated effective date for the 2007 rule amendment was October 1, 2007, the beginning of federal fiscal year 2008. *Id.* at 47,130.

Later, when the *Northeast Hospital* litigation was pending, the Secretary further revised that regulation by replacing "or" with "including" so that it now refers to patients who are "entitled to Medicare [p]art A (including Medicare Advantage ([p]art C))." 42 C.F.R. § 412.106(b)(2)(i)(B), (iii)(B) (2010); *see also* 75 Fed. Reg. 50,042, 50,285 (Aug. 16, 2010).

11. The agency did not begin to collect the data necessary to include part C days in the part A/SSI fraction until July 2007, when it instructed hospitals to submit data so that part C patient days could "be eventually captured in the DSH calculations." Change Request 5647, Transmittal No. 1311, at 1 (July 20, 2007);[4] *see also* Medicare Claims Processing Man. (CMS Pub. 100-04), ch. 3, section 20.3.[5]

[4] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1311CP.pdf.

[5] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c03.pdf.

B. Facts Specific To This Case

1. The Hospitals treat substantial numbers of low-income patients and thus are entitled to receive DSH adjustments to their part A payments.

2. In 2009, the Secretary published part A/SSI fractions for federal fiscal year 2007. AR 9; JA-. Those part A/SSI fractions were the first to include part C days, reducing the amount of the DSH adjustment to the Hospitals by more than 40 million dollars in the aggregate for just one year. *See* AR 13-20, 1192-1195; SAR 190, 419; JA-.

3. The Hospitals appealed to the Secretary's Board, which granted expedited judicial review, *see* 42 U.S.C. § 1395oo(f)(1), regarding the validity of the rule including part C days in the part A/SSI fraction. *See* AR 9, 11; JA-.

C. District Court Proceedings

The district court held the 2004 rule void *ab initio* because the Secretary provided inadequate notice and opportunity for comment on the regulation change and because the Secretary failed to explain her change in interpretation of the term "entitled to benefits under part A." Opinion ("Op.") 17-18; Order, ECF No. 47, at 2; JA-. The district court first concluded that the "Secretary's interpretation of the fractions in the DSH calculation, announced in 2004 and not added to the Code of Federal Regulations until the summer of 2007, was not a 'logical outgrowth' of the 2003 notice." Op. 22-23; JA-. The district court rejected the government's

invitation to "bootstrap notice from a comment," adding that the comments were "limited in number" and reflected, at most, "confusion and misunderstanding." Op. 25; JA-.

The district court also concluded that the 2004 rule change was unreasonable because the agency failed to acknowledge or explain the reversal of its prior policy, and because the 2004 rule contained no "reasoned explanation" at all but "merely restated the … problem." Op. 29-30; JA-. The district court detailed a list of factors that the agency failed to consider or explain in the 2004 rule, including inconsistency in the agency's interpretation of statutory terms, the need to reconcile the new policy with congressional intent, and logistical and financial concerns regarding the new policy. Op. 30; JA-.

The court vacated the 2004 rule, Op. 32; JA-, and did not reach the Hospitals' contention that the change was inconsistent with the intent of the DSH statute, Op. 26; JA-.

SUMMARY OF ARGUMENT

The government's brief presents a series of contradictions. It claims to accept the holding of this court in *Northeast Hospital* that the agency in 2004 effected a rule change that could not be applied retroactively, but argues at the same time that there was no change to "binding" policy requiring acknowledgement and explanation. The government alternatively asserts that,

despite the agency's "clarification" responding to questions about the rule in place in 2003, the hospitals should have understood some clear message that the agency had put an imminent policy reversal on the table. What is more, the government offers a host of *post hoc* rationalizations for the 2004 rule change that nowhere appear in either the 2003 clarification or the 2004 final rule. This approach, of course, only highlights the mixed messages and afterthoughts that pervaded the agency's convoluted process for adopting and implementing the rule change.

Enough is enough. This Court already concluded that the agency made a change in 2004. But the agency did not give notice of any proposed rule change. The agency failed (and still fails) to acknowledge the change in course, and provided no reasonable explanation for the change. Perhaps that is because it cannot, as the new approach reflects an inconsistent interpretation of "entitled," and is inconsistent with even the agency's understanding of Congress's intent, reflected in other regulations governing the DSH adjustment to the Medicare part A payment rates. The district court's vacatur of the agency's procedurally and substantively invalid rule is correct.

1. The 2004 final rule must be evaluated against the reality, recognized by this Court, that it represented a sharp departure from the agency's prior longstanding rule. After the 1997 enactment of part C, the agency interpreted "entitled to benefits under part A" not to include part C days. Accordingly, this

Court previously resolved that the 2004 rule effected a policy reversal. In any event, circuit law does not grant the agency license to lurch from one policy to the opposite as long as the agency remains silent about what it was doing.

2. The agency's 2003 clarification did not provide adequate notice of, or an opportunity to comment on, the 2004 rule reversal. A final rule can only be a logical outgrowth of an actual proposed rule, and it must give warning that the agency is considering an about-face. The agency did not propose any amendment to the 1986 regulation, solicit comment, or provide any indication that the agency was considering changing its existing rule regarding part C days. The agency's clarification in 2003 does not allow the agency to pull a surprise switcheroo on the regulated industry and adopt the entirely opposite rule in 2004.

Nor can the agency manufacture adequate notice from the sparse comment record. That maneuver is prohibited by circuit law, which requires the agency itself to provide notice of a proposed rule change. Moreover, none of the comments demonstrates an understanding that the rule change announced in 2004 was on the table in 2003. Rather, to the extent that a few commenters suggest the regulated industry believed a policy change had been proposed, it was only because they held an erroneous view (never corrected by the agency) of the agency's then-governing interpretation of its 1986 rule regarding part C days.

The government cannot escape its failure to provide adequate notice and comment by asserting harmless error. The Medicare statute provides no harmless-error exception to vacatur for the agency's failure to provide notice and comment. And circuit precedent does not require the Hospitals to prove that the agency would have taken a different course had notice been provided. The Hospitals would have had much to say if the agency had actually said what it was doing, which the Secretary presumably would have considered, and thus surmount any requirement to show some uncertainty as to the outcome.

3. Even if adopted properly, however, the 2004 rule change is still invalid because it represents an unreasonable and impermissible statutory interpretation. First, the agency failed altogether to acknowledge its reversal of longstanding policy, which itself renders the interpretation unreasonable. Second, the agency made no reasoned explanation of her 2004 rule whatsoever, which would doom the rule even if written on a clean slate. This utter failure to grapple with significant issues—some of which the government does not claim to have addressed—is not reasoned decisionmaking. Finally, the 2004 rule is impermissible because it cannot be squared with the congressional intent of the DSH payment, as understood even by the agency, to provide additional Medicare part A payments for services to low-income patients.

4. Finally, the district court's remedial order was proper. As the government concedes, vacatur is required for its failure to meet notice-and-comment requirements. The agency's failure to explain the 2004 rule change likewise demands vacatur. And that vacatur restores the previously governing rule excluding part C days from the part A/SSI fraction. Because the agency may not depart from this prior rule without undertaking a new, valid rulemaking, which could operate only prospectively, the agency cannot continue as if its vacated rule were in force and apply that vacated rule to hospitals unless it is re-promulgated.

ARGUMENT

I. STANDARD OF REVIEW

The agency's rule cannot stand if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (incorporated by reference in 42 U.S.C. § 1395oo(f)(1)). When an agency "promulgate[s] final rules that differ from the proposed rule," this Court may uphold the agency's rule only if it was a "logical outgrowth of a proposed rule," which does not "extend to a final rule that is a brand new rule." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

The Secretary's statutory interpretation is reviewed under *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). If the statute is

ambiguous, the Court may defer to the agency's interpretation only if it falls within "the bounds of reasonableness," *Goldstein v. SEC*, 451 F.3d 873, 881 (D.C. Cir. 2006). The agency must acknowledge and explain departures from prior policy, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), be internally consistent, *Air Line Pilots Ass'n v. FAA*, 3 F.3d 449, 453 (D.C. Cir. 1993), and show "how [the] agency's interpretation serves the statute's objectives." *Northpoint Tech. Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005).

II. THIS COURT PREVIOUSLY RULED THAT THE AGENCY CHANGED ITS POLICY IN 2004

In *Northeast Hospital*, this Court concluded that the Secretary could not apply the 2004 rule change to earlier fiscal years because, under the prior rule, "the Secretary routinely *excluded* [part C] days from the Medicare [part A/SSI] fraction." 657 F.3d at 15. Responding to the government's attempts to avoid this holding, the district court correctly followed *Northeast*'s ruling that the 2004 rule "contradicts" and is a "substantive departure" from the agency's application of the prior rule to part C patient days. Op. 20; JA- (quoting *Northeast Hosp.*, 657 F.3d at 17). The government's more subtle yet continued efforts to avoid this holding must fail.

Here, the government portrays the 2004 rule change as the agency's first foray into the policymaking arena, reasserting the already-rejected position that the agency had no "binding" or "authoritative" policy to include or exclude part C

days in part A/SSI fraction before 2004. *See, e.g.*, Gov. Br. 25 n.5, 27, 34, 43. *Northeast* rejected this argument on the ground that it was "belie[d]" by the agency's actual treatment of part C days, 657 F.3d at 15, and found that the Secretary "changed her *interpretation* of the DSH provision in 2004," *id*. at 16 (emphasis added). This Court has likewise already rejected the Secretary's argument (Gov. Br. 31) that a 1990 statement regarding other HMO days (which were covered under part A) reflected her binding policy on part C days under the new program established in 1997. *See* 657 F.3d at 16 ("Again, however, her actual practice belies this claim.").

The Secretary's further assertion that *Northeast Hospital* did not address the Medicaid fraction, Gov Br. 32, is nonsensical. That case involved both fractions, and this Court affirmed Judge Bates' ruling that Medicaid-eligible days for part C patients must be included in the Medicaid fraction. 657 F.3d at 2; *Northeast Hosp. Corp. v. Sebelius*, 699 F. Supp. 2d 81, 93-94 (D.D.C. 2010). The Hospitals agree with this Court that, under the Medicare statute, a part C patient is either entitled to part A or not, for both the Medicaid and part A/SSI fractions. *Northeast Hosp.*, 657 F.3d at 5. But this case concerns the part A/SSI fraction. *See* Op. 11; Complaint ¶ 72(B); JA-.

Unlike the part A/SSI fraction, the Medicaid fraction is calculated by the agency's contractors, not the agency itself. Accordingly, even if there was

"variation" in how the Medicaid fraction was calculated from one intermediary to the next, which the agency has never established, *see* 68 Fed. Reg. at 27,416 (stating only that such variation "appears likely"), it would have no bearing on the certainty of the agency's legal interpretation of "entitled to benefits under part A" as excluding part C patients from the part A/SSI fraction under the agency's 1986 regulation specifying that only days "covered" by part A may be included in that fraction, 42 C.F.R. § 412.106(b)(1). The only conceivable "change" in 2003, 68 Fed. Reg. at 27,416, was that the agency was finally making its interpretation clear to its contractors, Gov. Br. 34. Confusion by the contractors does not mean that the agency rule was not already well-established.

Even apart from the *Northeast Hospital* ruling, the government's argument that the agency's consistent practice over many years before 2004 did not establish a "binding legal interpretation," Gov. Br. 31, contravenes the law of this Circuit. After the part C program was enacted in 1997, the agency consistently applied the 1986 regulation to exclude part C patient days from part A/SSI fractions that it calculated for thousands of hospitals per year until fiscal year 2007. *See Northeast Hosp.*, 657 F.3d at 15 ("the Secretary never count[ed] [part C] days in the [Medicare] fraction except rarely, and then by mistake"); 78 Fed. Reg. 27,486, 27,590 (May 10, 2013) (estimating that 2,349 hospitals would qualify for DSH adjustments in 2014). A practice "initiated and carried out by members of the

[agency's] staff," can be "repeated … for so long that it [bears] the [agency's] imprimatur." *Aliceville Hydro Assocs. v. FERC*, 800 F.2d 1147, 1151 (D.C. Cir. 1986) (per curiam). When a practice is "long-standing," regulated entities are "entitled to look upon the practice as an expression of [agency] policy just as they might look to the [agency's] regulations." *Id.*; *see also Arkema Inc. v. EPA*, 618 F.3d 1, 7-8 (D.C. Cir. 2010) (rejecting agency's argument that its "policies are evidenced by its express statements" rather than its practice because "the [a]gency's practices supported Petitioners' position" as to the agency's policy); *Mercy Med. Skilled Nursing Facility v. Thompson*, No. 99-2765, 2004 WL 3541332, at *3 (D.D.C. May 14, 2004) ("[W]hether it is written down or not, a consistent ten-year practice of granting atypical cost exceptions in the same manner year after year reflects a 'definitive' interpretation of the relevant authoritative text."). That standard is easily met here.

The *Northeast* ruling on the Secretary's policy and practice before the 2004 rule change is binding here, *N.Y.-N.Y., LLC v. NLRB*, 676 F.3d 193, 194-195 (D.C. Cir. 2012), and the Secretary has offered no acceptable basis for departing from that holding, Op. 19; JA-.

III. THE AGENCY'S POLICY CHANGE WAS PROCEDURALLY INVALID

A. The 2004 Final Rule Was Not The Logical Outgrowth Of Any Proposed Rule

The district court correctly held that the 2004 rule change was not a "logical outgrowth" of the 2003 clarification. Op. 22; JA-. The "logical outgrowth" test presupposes that there is a prior proposed *rule*, and requires the notice of the proposed rule to give an "indication that the agency was considering a different approach." *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009). The Secretary's 2003 clarification proposing no regulation change, soliciting no comments, and giving no hint of a change in interpretation of the prior regulation, does not qualify. Moreover, comments by the public on the proposed clarification cannot substitute for the lack of notice by the *agency* of a proposed rule change. *See Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) (agency "cannot bootstrap notice from a comment").

1. The Agency's 2003 Clarification Did Not Give Notice Of A Proposed Rule Change

The agency announced in 2004 that it was "adopting a policy" and "revising [its] regulation" in order to include part C days in the part A/SSI fraction. 69 Fed. Reg. at 49,099; *see also Northeast Hosp.*, 657 F.3d at 16 (Secretary "changed her interpretation of the DSH provision in 2004"). This rule change required notice and comment rulemaking under the APA and the Medicare Act. *See* 5 U.S.C.

§ 551(4) (defining "rule" to include the repeal or amendment of a rule); 42 U.S.C. § 1395hh(a)(2) (rule that "changes a substantive legal standard governing … payment for services" must be "promulgated by the Secretary by regulation").

A final rule must be a "'logical outgrowth' of the agency's proposed regulations." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 442 (D.C. Cir. 2012). This requires a proposed regulation, *cf. Kooritzky v. Reich*, 17 F.3d 1509, 1513 (D.C. Cir. 1994) ("Something is not a logical outgrowth of nothing."), that provides the regulated industry fair warning that the agency is considering changing its existing regulatory approach, *CSX Transp.*, 584 F.3d at 1081. The rule change announced in 2004 does not meet this test.

First, the agency proposed no regulation amendment regarding part C days. *See* 68 Fed. Reg. at 27,229; Op. 23; JA- (agency "nowhere propos[ed] any amendment to the C.F.R."). The 2003 clarification is thus not "something" from which a final rule amending the regulation could grow. *Cf. Kooritzky*, 17 F.3d at 1514. The agency "may not introduce [its] proposed rule in this crabwise fashion." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1322-23 (D.C. Cir. 1988) (notice inadequate where agency invited comments on a proposed policy but identified it as a proposed "[a]pproach" rather than a rule).

Second, the agency did not solicit comments of any kind, never mind indicate any change to the established rule was under consideration. The agency

merely clarified, in response to "questions," how the agency had been handling part C days under its 1986 regulation since part C was enacted in 1997. *See* 68 Fed. Reg. at 27,208; *Northeast Hosp.*, 657 F.3d at 14-17. Contrary to the government's paraphrase, Gov. Br. 28, the agency did not propose to clarify "whether" an individual receiving benefits under part C remains entitled to benefits under part A. Rather, the agency "propos[ed] to clarify *that* once a beneficiary elects Medicare Part C, those patient days … should not be included in the Medicare [part A/SSI] fraction," 68 Fed. Reg. at 27,208 (emphasis added). The agency answered the "questions" by explaining only that "once a beneficiary has elected to join a [part C] plan, that beneficiary's benefits are no longer administered under Part A," and accordingly the days must be excluded from the part A/SSI fraction and included in the Medicaid fraction to the extent the patients were Medicaid eligible. *Id.*

The government's argument fails to account for the agency's common terminology within a notice of proposed rulemaking. A comparison to other parts of the same 2003 notice confirms that the agency uses the term "propos[al] to clarify" to refer to codifications or restatements of longstanding policy. *See*, *e.g.*, *id*. at 27,202, 27,204 ("proposing to clarify that beds and patient days counted for [particular] purposes should be limited" in a particular way and the agency was "proposing to revise [its] regulations" only "to be more specific"); 68 Fed. Reg. at

27,205 (announcing clarification consistent with the agency's "longstanding interpretation of the statutory intent").

It is common for the Secretary to use the phrase "proposing to clarify" when she is merely stating a clarification of what current policy is and proposing no change. For example, in a 2009 notice of proposed rulemaking, the Secretary stated she was "proposing to clarify" her policy about new medical residency programs, 74 Fed. Reg. 24,080, 24,192 (May 22, 2009), after it had come to the Secretary's attention that "there has been some misinterpretation or misunderstanding ... among some hospitals and Medicare contractors," *id.* at 24,191. The Secretary had not proposed a change, but simply clarified what her policy already was, as she explained in the final rule: "the policy discussed in the proposed rule is ... a clarification," not a "'major' policy change." 74 Fed. Reg. 43,754, 43,910 (Aug. 27, 2009). The same is true here.

On the other hand, when the Secretary intended to give notice that she was proposing to adopt or revise a policy in 2003, she said so. The Secretary's 2003 approach to part C days stands in stark contrast to her approach in the same document regarding patients whose Medicare coverage has been exhausted. There, the Secretary gave explicit notice that she was "proposing to change [her] policy." 68 Fed. Reg. at 27,207. Likewise, in another proposal relating to the DSH payment, the Secretary explicitly "propos[ed] to amend [its] policy with respect to

observation bed days." *Id*. at 27,206. She also expressly sought comments on specific proposed policies. *See, e.g.*, *id*. at 27,189 ("soliciting comments on our policy"); *id.* at 27,203 ("encourag[ing] comments" related to the "policy that [it is] proposing"); *id.* at 27,209 ("soliciting comments on whether it may be appropriate to establish a [particular] policy").

Not so for the Secretary's clarification on part C days, which proposed no change and invited no comment on any interpretive questions. A "final rule represents a logical outgrowth where the [notice of proposed rulemaking] expressly asked for comments on a particular issue or otherwise made clear that the agency was contemplating a particular change." *CSX Transp.*, 584 F.3d at 1081. The agency did neither in 2003, and the 2004 policy reversal was accordingly adopted without the required notice and opportunity for comment.

The agency's tack of proposing to clarify its existing policy and then amending the rule to reverse that policy was, like in *Environmental Integrity Project*, an invalid "flip-flop." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 997 (D.C. Cir. 2005). In that case, this Court considered a rulemaking notice in which the EPA "propos[ed]" to remove language from its regulations in order to "clarify" its policy in response to "numerous requests from permitting authorities and citizens requesting clarification." 67 Fed. Reg. 58,561, 58,564 (Sept. 17, 2002). The proposed clarification matched the EPA's then-prevailing practice. *Envtl.*

Integrity Project, 425 F.3d at 997. The final rule "did not adopt the proposed interim rule" clarifying existing policy, but "adopted a 'reinterpretation' of the unamended text." *Id.* This Court rejected that "surprise switcheroo on regulated entities," finding inadequate opportunity for comment. *Id.* at 996.

The same result is warranted here: "[A]fter taking its first bite at the interpretive apple" by initially adopting an interpretation excluding part C days from the part A/SSI fraction, the Secretary cannot adopt a "reinterpretation" without advance notice. *See id.* at 997. That reversal of the Secretary's established interpretation of the DSH statute and the 1986 regulation regarding part C days required advance notice that the agency was "considering repudiat[ing] its proposed interpretation and adopt[ing] its inverse." *Id.* at 998.

The Secretary's reasons for distinguishing *Environmental Integrity Project* lack substance. The agency's contention that its policy was less established than the EPA's (Gov. Br. 31-33) simply repeats arguments made, and rejected, in *Northeast*. *See Northeast Hosp.*, 657 F.3d at 14-17. The government also insists that the Secretary said she was "'*proposing*' to exclude Part C days" and thus the clarification did not say the agency was clarifying longstanding policy of excluding part C days from the part A/SSI fraction. Gov. Br. 27. But the agency did *not* say it was "proposing to exclude part C days"—the agency said it was "proposing to *clarify* that once a beneficiary elects Medicare Part C, those patient days … should

not be included in the [part A/SSI] fraction." 68 Fed. Reg. at 27,208 (emphasis added).

Given the agency's longstanding policy of excluding part C days from the part A/SSI fraction under the 1986 DSH regulation, *Northeast Hosp.*, 657 F.3d at 15, and the agency's contemporaneous characterization of its writing as a "propos[al] to clarify" that policy, the government blinks reality when it now characterizes the 2003 clarification as proposing to "*adopt* an official policy to *either include or exclude* Part C days from the [part A]/SSI fraction," Gov. Br. 27, (emphasis added). The agency had already adopted an "official policy" of excluding part C days from the part A/SSI fraction. *Northeast Hosp.*, 657 F.3d at 16.

At most, using the government's words, the agency "proposed" only to provide an "authoritative statement of Medicare payment policy" (Gov. Br. 28) that part C days should be excluded from the part A/SSI fraction, just as the EPA proposed to provide an authoritative statement of its then-governing policy in *Environmental Integrity Project*. Even accepting the government's assertion that

the agency only proposed, newly, to "codify" its policy "in binding regulations," *see* Gov. Br. 34, this case falls squarely under *Environmental Integrity Project*.[6]

Indeed, the agency's citation to "likely … variation" in how part C days were handled "from one hospital and fiscal intermediary to the next," Gov. Br. 33-34 (quoting 68 Fed. Reg. at 27,416), proves the point. There was no variation with respect to how the agency handled part C days in *its calculation* of the part A/SSI fraction. *Northeast Hosp.*, 657 F.3d at 15 ("[T]he Secretary routinely excluded M+C days from the [part A/SSI] fraction."). The only potential variation was among *contractors*, not understanding the agency's policy, with respect to the Medicaid fraction they themselves calculated. As the government recognizes, *see* Gov. Br. 34, it was in the context of discussing that potential Medicaid fraction variation that the agency referred to a "proposed change" with respect to part C days. Even then, the agency reiterated that it was "proposing to clarify" that part C days should be included in the Medicaid fraction. 68 Fed. Reg. at 27,416.

This "proposed change" reference cannot be read to mean "policy change," because *that* would be flatly incorrect, *Northeast Hosp.*, 657 F.3d at 16. Misinforming the public does not improve the quality of the agency's notice. *See*

[6] The agency did not actually codify any policy until 2007, and then only in a regulation amendment adopted without *any* notice, and effective only prospectively, beginning on October 1, 2007, after the fiscal years at issue. *See* 72 Fed. Reg. at 47,384.

Conn. Light & Power Co. v. NRC, 673 F.2d 525, 530 (D.C. Cir. 1982) (proposed rulemaking must "provide an accurate picture of the reasoning that has led the agency to the proposed rule, [or] interested parties will not be able to comment meaningfully upon the agency's proposals."). Even if it *could* be read as a policy change with respect to the *Medicaid* fraction, *see* Gov. Br. 34, the government's suggestion that part C days could have been excluded from the DSH calculation altogether before 2004 simply underscores that hospitals could not have known that the Secretary was proposing a "binary choice" between the two fractions, *see* Gov. Br. 26, and should be forgiven for not divining the government's unspoken intent.[7]

Finally, the 2003 clarification was very different from the notices in the two cases upon which the Secretary principally relies. In *Nuvio Corp. v. FCC*, 473 F.3d 302 (D.C. Cir. 2006), the notice expressly stated that the agency was for the first

[7] The agency issued two Federal Register statements, prior to the 2004 final rule, promising to respond to comments on the 2003 clarification. *See* 68 Fed. Reg. 45,346, 45,422 (Aug. 1, 2003); 69 Fed. Reg. 28,196, 28,286 (May 18, 2004). The government has waived any argument that those statements supplied the requisite notice. In any event, the statements demonstrate that the agency failed to avail itself of multiple opportunities to provide notice. They neither described the comments received nor gave any indication that the agency was considering a change in policy. The 2004 statement described the 2003 clarification as a "proposed change[]." 69 Fed. Reg. at 28,286. But, again, that characterization of the clarification either indicates a codification of Medicaid fraction policy, or is wholly inaccurate.

time "deciding whether to exercise [its] regulatory authority" over certain services and sought "comment in this proceeding" relating to those services, IP Enabled Servs., 19 F.C.C.R. 4863, 4898 (2004). In that context, the agency did not need to specify particular proposed rules because it "fairly apprised the parties and the public of the issues covered by the [final rule]." 473 F.3d at 310. The Secretary here did not identify the treatment of part C days as an issue she intended to resolve, but rather as an area she had already resolved.

Likewise, in *Northeast Maryland Waste Disposal Authority v. EPA*, 358 F.3d 936 (D.C. Cir. 2004), the agency announced a proposal to begin distinguishing between "refractory and nonrefractory units," taking its first step in addressing the subject. *Id.* at 952. In that context it might be reasonable for regulated entities to believe that every option is on the table. But when an agency has already taken a regulatory approach, it must provide fair warning if it is considering a complete reversal in position. *See Envtl. Integrity*, 425 F.3d at 997; *see also Nat'l Mining Ass'n v. MSHA*, 116 F.3d 520, 531 (D.C. Cir. 1997) (finding notice inadequate to revise long-standing practice although "it might well have been reasonable to think that all aspects of the rule were on the table" if the notice "had been the agency's first attempt to regulate preshift examinations").

The district court therefore did not err in considering that the 2004 rule adopted the inverse of what the 2003 notice clarified. Op. 23; JA-. As the district

court acknowledged, a 180-degree shift from proposed rule to final rule is not "a *per se* death knell." *Id.* But neither does a policy reversal "make[] no difference" whatsoever, as the government would have it, Gov. Br. 15. Because "the final rule revealed that the agency had completely changed its position," and the agency "gave no indication that the agency was considering a different approach," the 2004 rule fails. *See CSX Transp.*, 584 F.3d at 1081.

2. The Agency Cannot Manufacture Notice Out Of Commenters' Confusion

The Secretary's failure to provide notice for the rule change announced in 2004 is not cured by the comments the agency received on the 2003 clarification of the prior rule. It is well-established that an agency "cannot bootstrap notice from a comment." *Fertilizer Inst.*, 935 F.2d at 1312. "[A]mbiguous comments and weak signals from the agency" are not sufficient to give interested parties the "opportunity to anticipate and criticize the rule or to offer alternatives." *Int'l Union*, 407 F.3d at 1261. The government's claim that the comments "demonstrate that providers plainly understood the two possible outcomes of the rulemaking," Gov. Br. 36, is wrong on the law and the facts.

First, this Court has recently rejected a similar attempt by an agency to "avoid" the rule that the agency "must *itself* provide notice of a regulatory proposal" by contending that comments "demonstrate[d] that the [agency] provided adequate notice." *Ass'n of Private Sector Colls.*, 681 F.3d at 462. Where

"at least some of the commenters … merely requested clarification … without offering evaluations of the final rule," the agency cannot rely on the comments to supply the requisite notice and this Court "cannot conclude that the purposes of notice and comment have been served." *Id.* The same is true here. *See, e.g.*, RR 516; JA- (Question from the Secretary's contractor: "Does the proposal mean that M+C days were included in the SSI% prior to this proposal, and will no longer be included in the SSI%?").

The cases relied upon by the government (Gov. Br. 36) are not to the contrary. Both hold that a final rule satisfied the "logical outgrowth" test because the *notice* at issue conveyed to regulated entities the need "to present relevant information." *Nuvio Corp.*, 473 F.3d at 310 (citing four places in the notice itself that provided the relevant warning to the industry and noting, only after concluding that the *notice* was sufficient, that "many of the parties submitted comments"); *Appalachian Power Co. v. EPA*, 135 F.3d 791, 816 (D.C. Cir. 1998) (concluding that notice was sufficient because the agency actually proposed a rule, it "did solicit comments regarding" the relevant topic, and "modification of a proposed rule, in response to the comments [the agency] *solicited* and received on alternative possibilities" satisfies the APA) (emphasis added). Here, as discussed above, the agency did not propose a change to its regulation before the 2004 final rule, did not solicit comments on any proposed regulation amendment, and did not put regulated

parties on notice of the need to submit them. The Secretary, therefore, cannot rely on the comments to supply the requisite notice that the agency itself failed to provide. *Int'l Union*, 407 F.3d at 1261.

Second, the pittance of comments received, totaling about 26 pages, hardly suggests an industry understanding of a possible about-face, particularly where hundreds of millions of dollars were at stake.

This comment record is incredibly thin. *See* Op. 25; JA-. By way of comparison, the agency recently proposed to adopt the same rule vacated below, and a review of only those comments available online indicates that proposal yielded at least double the number of comments, from entities representing thousands and thousands of hospitals (and overwhelmingly opposing the proposed policy).[8]

The substance of the comments likewise displays that regulated parties had no inkling that the 2003 clarification was actually a proposal for the policy change

[8] Comments on the proposed rule available electronically may be found at http://www.regulations.gov. The agency states that it began a new proposed rulemaking in March 2013 "in an abundance of caution" in light of the district court's vacatur of the 2004 rule. *See* 78 Fed. Reg. 27,486, 27,578 (May 10, 2013). The government does not claim, nor could it, that the final rule adopted in this rulemaking could be retroactively applied. *See Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) ("The Secretary's suggestion that retroactive rulemaking is permissible to remedy a procedural defect in a rule would, if accepted, make a mockery of the provisions of the APA.").

announced in the 2004 final rule. The government notes some comments "opposing" the 2003 clarification, recommending instead that part C days "*continue* to be counted as Medicare days." Gov. Br. 35 (emphasis added). But those comments merely reflect the erroneous belief that the Secretary was already including part C days in the part A/SSI fraction. To the extent they could be read to anticipate a policy change, that is only because they misunderstood the agency's longstanding practice—*not* because the agency itself gave any clue of a possible regulatory reversal. The same goes for the comments mentioning "operational concerns" with respect to a purported policy change. Gov. Br. 36. Those comments do not show that the agency itself had given *notice* of the rule change it later announced in the 2004 final rule.

The other comments highlighted by the government, which it contends "agreed with the agency's proposal to exclude the Part C days from the Medicare/SSI fraction," Gov. Br. 35, in fact confirm that some members of the regulated community understood that the Secretary was proposing nothing more than a restatement of her *existing* policy of excluding part C days from the part A/SSI fraction. Accordingly, they certainly do not suggest that those commenters

were on notice that the agency was proposing to change its regulation, nor do they address the interpretation of the statute that the agency adopted.[9]

Any confusion exhibited by the commenters would not be surprising in light of the agency's practice in calculating the part A/SSI fraction, which left some hospitals in the dark. Because the part A/SSI fraction is calculated entirely by the agency, using privacy-protected data, the agency was able to regulate from the shadows, and hospitals had no way to know for sure what patient days the agency was or was not including in that fraction. *See Baystate Med. Ctr.*, 545 F. Supp. 2d at 23-24. The Hospitals are thus quite in agreement that "there was confusion among providers and intermediaries." Gov. Br. 37. Hence the need for clarification. That, however, does not mean that the *Secretary* did not know how the agency had for years interpreted the 1986 regulation regarding part C days in its own calculations of the part A/SSI fractions for thousands of hospitals.

[9] *See, e.g.*, RR 144 ("It appears that the only time [part C days] are counted is when CMS makes an error in the processing of the [part A/SSI] calculation."); RR 147-149 ("As evidenced by a recent clarification of CMS policy, the days of a dual eligible who has enrolled in Medicare+Choice are not included in the [part A/SSI] fraction."); RR 389-90 ("[T]he Medicare+Choice dual eligible days were excluded from the [part A/SSI fraction]"); RR 490; RR 554 ("[I]t appears that the SSI fraction generally does not include Medicare HMO days"); JA-.

B. The Hospitals Were Prejudiced By The Agency's Failure To Provide Notice Of Its 2004 Rule Change

The district court properly rejected the government's contention, Gov. Br. 38-39, that the agency's failure to provide notice of the 2004 regulation change was a harmless error. Op. 26-27; JA-. The Hospitals were prejudiced, no matter how you slice it.

First, the "prejudice" requirement of the APA does not apply here, where the Medicare statute itself mandates the remedy for a final rule that is not a logical outgrowth of a proposed rule: it "shall be treated as a proposed regulation and shall not take effect until there is a further opportunity for public comment." 42 U.S.C. § 1395hh(a)(4). Unlike the APA, which refers to "due regard for the rule of prejudicial error," 5 U.S.C. § 706(2), the Medicare statute contains no harmless-error exception.

Second, as the district court correctly found, this Court does not "require[] a particularly robust showing of prejudice in notice-and-comment cases." *Chamber of Commerce v. SEC*, 443 F.3d 890, 904 (D.C. Cir. 2006). The decision in *Chamber of Commerce* did not alter that standard for logical outgrowth errors because this Court found no logical outgrowth error in that case. *Id.* at 901. It held only that the particular notice-and-comment error before it—the failure to notify parties of the agency's intent to rely upon particular studies—did not "involve the outright dodge of APA procedures that led the court to permit a limited showing of

prejudice" in other kinds of notice-and-comment cases. *Id.* at 904. This Court has *rejected* any bright line rule requiring "petitioners in all 'logical outgrowth' cases to show what additional comments they would have submitted had notice been adequate," *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003).

Third, the government proves too much in asserting that any failure to provide adequate notice "did not affect the outcome." Gov. Br. 40. A closed minded approach to rulemaking is precisely what the APA and the Medicare Act are meant to foreclose, not encourage. *See Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991) (when final rule was not logical outgrowth, agency had "entirely failed to comply with notice-and-comment requirements" and prejudice established because court could not "say with certainty whether petitioner's comments would have had some effect if they had been considered when the issue was open"); *Nat'l Tour Brokers Ass'n v. United States*, 591 F.2d 896, 902 (D.C. Cir. 1978) (The APA requires advance notice and comment in order to provide an agency the benefit of parties' "expertise and input" in the decisionmaking process, when the agency still has a "flexible and open minded attitude towards its own rules."). In any event, the government relies on a case addressing the failure to adequately explain a departure from prior agency policy in an adjudication, not the failure to provide adequate notice and comment for a new rule. *See PDK Labs. Inc. v. U.S. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004). In the rulemaking context, a party need not show

that "that the [agency] would have reached a different result" if the party had been given notice and an opportunity to comment on a proposed new rule. *Chamber of Commerce*, 443 F.3d at 905.

Fourth, the government wholly ignores the *substantive* prejudice of the 2004 rule change to hospitals nationwide, which amounts to hundreds of millions of dollars per year. *Northeast Hosp.*, 657 F.3d at 5 ("Nationwide, the practical consequences of this dispute number in the hundreds of millions of dollars."). As the government's own authority shows, whether the final rule helps or harms the parties seeking review is part of the prejudice analysis. *See Am. Coke & Coal Chems. Inst. v. EPA*, 452 F.3d 930, 941 (D.C. Cir. 2006) (no prejudice where final rule "resulted in a less stringent limitation across the board"); *First Am. Discount Corp. v. CFTC*, 222 F.3d 1008, 1016 (D.C. Cir. 2000) (declining to decide whether final rule was logical outgrowth because final rule created an option that "was not harmful, or … less harmful" than what was proposed). The loss to safety net hospitals of hundreds of millions of dollars is tragic, not harmless.

Fifth, even if the Hospitals needed to show "enough [un]certainty whether [their] comments would have had some effect," *Chamber of Commerce*, 443 F.3d at 904, the Hospitals easily meet that standard. The response would have been very different had the agency made clear that it was proposing to *change* what it was doing in order to *include* part C days in the part A/SSI fraction and thereby

suppress DSH payments by hundreds of millions of dollars per year. When the agency published part A/SSI fractions for 2007, including part C patient days for the first time, the fractions dropped dramatically, and hospitals pressed the agency for data to understand the reduction in the fractions. *See* CMS, Disproportionate Share Hospital (DSH): Note to Providers on the FY 2007 SSI Ratios (as displayed May 13, 2010) (noting that the agency "posted additional information" regarding part C days "[a]t the request of several hospitals").[10] And, hospitals, like Appellees, immediately challenged the rule change as applied in those fractions for 2007. *See* AR 9; JA-.

As noted by the government, Gov. Br. 39, a few plaintiff Hospitals submitted comments on the clarification. They supported both (1) continuing the status quo, and (2) including part C days in the part A/SSI fraction. But that two part position was an impossibility since part C days had not, in fact, ever been counted in the part A/SSI fraction before the 2009 calculation of the fiscal year 2007 fractions. Once those hospitals became aware that the agency was departing from the status quo, and that the change would have a significant financial impact, their comments

[10] *Available at* http://web.archive.org/web/20100513052149/http://www.cms.gov/AcuteInpatientPPS/05_dsh.asp. These data show that, nationwide, 9.7 percent of Medicare part A fee for service patients are entitled to SSI, but only 5.8 percent of part C patients are entitled to SSI.

were very different, as demonstrated by this action and by recent comments.[11] For example, both North Shore Long Island Jewish Health System and the Association of American Medical Colleges (representing several hundred of teaching hospitals, health systems, and medical schools), whose 2003 comments the government invokes, Gov. Br. 35, have opposed the agency's 2013 proposal. In addition, the American Hospital Association (representing about 5000 hospitals), which did not even comment on the 2003 clarification, has submitted two pages of comments in opposition to the 2013 proposal. And numerous other commenters have highlighted, among other issues, that the agency's reading of the statute is inconsistent with congressional intent (*e.g.*, American Hospital Association, Federation of American Hospitals), is inconsistent with other aspects of the agency's past and present policy (*e.g.*, Louisiana Hospital Association, Trinity Health), and decreases payments to providers serving vulnerable populations (*e.g.*, University of California Health System, California Hospital Association).

If the agency had given notice and provided data regarding the potential financial impact of a proposed rule change to start including part C days in the part A/SSI fraction, hospitals could have made the kind of comments they have made now that the agency's policy switch and the underlying data are known. They

[11] These comments are available electronically through the search engine at www.regulations.gov.

could have evaluated and commented on the consequences of that kind of loss of funds for the nation's safety net hospitals, and the incompatibility of the rule change with the purpose of the DSH statute. They would have explained what the data show, that part C beneficiaries "are less likely to qualify for SSI benefits than non-[part C] enrollees," and that including them in the part A/SSI fraction significantly "decreases the DSH adjustment" payments. *Northeast Hosp.*, 657 F.3d at 5. Given that the agency's estimate of the impact of its change was woefully inadequate, *compare* 69 Fed. Reg. at 49,770 (estimating less than $50 million in impact for four changes to DSH, combined), *with Northeast Hosp.*, 657 F.3d at 5 (noting an impact of hundreds of millions of dollars per year), there is more than "enough uncertainty" that, if the agency had given notice of a proposed rule change and provided some of the data later produced, then hospitals would have submitted comments that might have convinced the agency not to change its rule. *See Chamber of Commerce*, 443 F.3d at 904 (alteration omitted).

Indeed, the Regulatory Flexibility Act (RFA), 5 U.S.C. § 605(b), is designed to avoid this kind of notice problem. It required the agency to make a reasoned judgment regarding the impact of her policy change on small entities, including most hospitals, 69 Fed. Reg. at 49,755. The Secretary was required to conduct a final analysis unless she "certifie[d] that the rule will not … have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b).

The Secretary's certification of no significant impact, 69 Fed. Reg. at 49,770, fell short of a "*reasonable*, good-faith effort" to evaluate the impact of the 2004 rule reversal. *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001). The 2004 change to the rule costs hospitals hundreds of millions of dollars in Medicare reimbursements per year. *See Northeast Hosp.*, 657 F.3d at 5. Even if hospital specific data was not available to the agency in 2003, the agency certainly had information identifying patients who were enrolled in part C, and could have "readily" (Gov. Br. 44 n.6) matched that enrollment data against the SSI entitlement data it regularly obtains from the Social Security Administration, *see Baystate*, 545 F. Supp. 2d at 24, to determine, in the aggregate, whether part C patients were less likely to be entitled to SSI than part A fee for service patients. In turn, the agency could have "readily" determined the aggregate payment impact produced by this differential.

The agency's insufficient analysis is an alternative ground for affirmance, although the district court did not reach this point argued by the Hospitals, Op. 18; JA-. This Court can consider the Secretary's "handling of these [RFA] issues … in determining whether [the Secretary] complied with the overall requirement that an agency's decisionmaking be neither arbitrary nor capricious." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 79 (D.C. Cir. 2000).

In sum, with proper notice, the Hospitals would have "had something useful to say," which is all that circuit precedent requires. *See Chamber of Commerce*, 443 F.3d at 905.

IV. THE SECRETARY'S NEW POLICY IS UNREASONABLE AND IMPERMISSIBLE

The Secretary's new policy does not pass muster under *Chevron* step two because it is "arbitrary, capricious, [and] manifestly contrary to the statute." *Chevron*, 467 U.S. at 844.[12] The 2004 rulemaking is unreasonable under *Chevron* step two because it failed to (1) acknowledge and (2) adequately explain the Secretary's change in position. *Northpoint*, 412 F.3d at 156. The 2004 rule is also unreasonable because it undermines "the policy judgments that undergird the statutory scheme." *Health Ins. Ass'n of Am. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994).

[12] The Hospitals concede that the panel is bound by this Court's holding in *Northeast Hospital*, 657 F.3d at 11, that the statute is ambiguous on the question presented. The Hospitals argued in the district court, and continue to contend, that the 2004 rule is inconsistent with the plain meaning of the statute. The retrospective language of the DSH statute, 42 U.S.C. § 1395ww(d)(5)(F), makes it "clear that HHS must count specific hospital days for patients who, on those specific days, were entitled to [p]art A benefits," and this would not include Part C days. *See* 657 F.3d at 19 (Kavanaugh, J., concurring). Recognizing that *Northeast Hospital* ruled otherwise, the Hospitals seek only to preserve the issue for en banc or certiorari review.

A. The Statutory Interpretation Announced In The 2004 Rule Is Unreasonable Under *Chevron* Because It Is Not The Product Of Reasoned Decisionmaking

1. The Agency Did Not Acknowledge Its Departure From Its Original Interpretation Of The DSH Statute

The Secretary's 2004 rule change did not meet the "core requirement" of reasoned decisionmaking when an agency changes policy in a rulemaking, *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012), that an agency not "depart from a prior policy *sub silentio* or simply disregard rules that are still on the books," *Fox*, 556 U.S. at 515. An agency must at least "'display awareness that it is changing position'" in a rulemaking. *Am. Elec. Power Serv. Corp. v. FCC*, 708 F.3d 183, 186 (D.C. Cir. 2013) (quoting *Fox*, 556 U.S. at 515). The purpose of this requirement is to ensure that an agency's "prior policies and standards are being deliberately changed, not casually ignored." *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089 (D.C. Cir. 2009).

The agency hardly "display[ed] awareness" in 2004 that it was "changing position," *Fox*, 556 U.S. at 515, and, to this day, the government still disclaims a policy change, *see* Gov. Br. 40-43. The 2004 rule change was therefore an utterly "unexplained departure from" the agency's prior "policy and practice," and it fails *Chevron* step two. *Northpoint*, 412 F.3d at 156; *accord King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988). The government's efforts to dodge the legal implications of this blatant failure do not work.

First, the district court applied the correct standard. The court recognized, and accepted, the government's argument, Gov. Br. 41, that a new interpretation is not subject to a heightened standard of review. Op. 28; JA-. Consistent with the precedent the government relies on here, the district court properly applied the rule that the agency must acknowledge and explain its change in position. *See* Op. 28-29; JA-; *Nat'l Home Equity Mortgage Ass'n v. Office of Thrift Supervision*, 373 F.3d 1355, 1360 (D.C. Cir. 2004) ("To be sure, an agency must provide a 'reasoned analysis' for its change in course….") (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983)).

Second, this Court has made clear that the "requirement of reasoned decisionmaking *demands*" that an agency acknowledge its changes in position, *Am. Elec. Power Serv. Corp.*, 708 F.3d at 186 (emphasis added), and "agency action is arbitrary and capricious if it departs from agency precedent without explanation." *Dillmon*, 588 F.3d at 1090. The government points to no case holding that an agency may depart from its prior rule without acknowledging that it is reversing course. Moreover, the government made no showing either in the district court or its brief as to any extraordinary circumstances that would have excused its failure to acknowledge its 2004 rule change. *See Fox*, 556 U.S. at 515 (reasoned decisionmaking "ordinarily demand[s] that [an agency] display awareness that it is changing position").

Third, the government's argument that the 2004 rule did not change an "authoritative agency legal interpretation," Gov. Br. 43, is a red herring. This—yet again—fights a battle that the government already lost. This Court has held that the Secretary "changed her interpretation of the DSH provision in 2004." *Northeast Hosp.*, 657 F.3d at 16. Regardless of whether the agency had previously described its years-long application of the 1986 regulation to part C days in a separate writing, there was a prior regulation limiting the part A/SSI fraction to days covered by part A, *see Catholic Health Initiatives-Iowa*, 2013 WL 2476896, at *6 n.5, "that required discussion" in the 2004 rule. *See* Gov. Br. 43. Moreover, circuit law does not allow an agency to veer willy-nilly between actual practices without comment or explanation. *See Northpoint*, 412 F.3d at 153-154 (reviewing agency's past practice to determine if new rule departed without reasonable explanation). And, the agency is not made better off under the law for obfuscating what it in fact *did*, according to agency policy.

The Supreme Court and this Court have concluded that the core requirement of reasoned decisionmaking precludes an agency from departing from rules on the books *sub silentio*, and the government offers no satisfactory reason why this Court should disregard the wisdom of that precedent in this case.

2. The Agency's 2004 Rule Provides No Reasoned Explanation For The Secretary's Policy

The agency also misses at *Chevron* step two because it does not "show that there are good reasons" for the new rule. *See Fox*, 556 U.S. at 515. The agency claims its "path may reasonably be discerned," Gov. Br. 45, but fails to find any crumbs in the *rule itself* that would demark the path.

The district court, rejecting the government's *post hoc* attempts to supply a rationale for the rule, found that the agency failed to address a litany of important considerations, some raised by comments. Op. 30; JA-. These included internal inconsistencies in the agency's statutory interpretation of "entitled" in the same sentence in the DSH statute; how (or whether) its policy furthered congressional intent; logistics of implementing the new policy, which took years; and the financial impact of its policy reversal. Op. 30; JA-; *see Athens Cmty. Hosp. v. Shalala*, 21 F.3d 1173, 1179-1180 (D.C. Cir. 1994) (refusing to consider rationale because "the Secretary did not rely upon [it]"). The Secretary herself "should have wrestled with" these issues. Op. 30; JA-.

Regarding its inconsistency in statutory interpretation, the government makes no response to the district court's finding on the agency's failure to explain "how regulated entities should reconcile the possibility of two different definitions of the word 'entitled' in the same sentence," referring to the agency's inconsistent interpretation of the exact same phrase "entitled to benefits" to mean eligibility for

purposes of Medicare and entitlement to payment of SSI for purposes of SSI. Op. 30; JA-. Accordingly, it has waived any argument that its decision was not unreasonable in this respect. *See Northpoint*, 412 F.3d at 156 (agency decision is arbitrary when it relies on "an unidentified … difference … to support its interpretation" to treat two similar issues inconsistently); *N.Y. Rehab. Care Mgmt., LLC v. NLRB*, 506 F.3d 1070, 1076 (D.C. Cir. 2007) ("[I]ssues not raised until the reply brief are waived.").

In any event, the government cannot plausibly identify anywhere in the 2004 rule where the agency itself grappled with this inconsistency, and *post hoc* rationalizations will not suffice. *See Village of Barrington v. Surface Transp. Bd.*, 636 F.3d 650, 660 (D.C. Cir. 2011) (this Court may consider "only the rationales the [agency] actually offered in its decision"). And, because the "entitled to benefits" concept is no different as between the two social insurance programs,[13] any attempted explanation would fail to resolve a fundamental inconsistency that

[13] Both the Medicare part A and SSI programs grant beneficiaries the right to have payments made in their name. *See* 42 U.S.C. §§ 426(c), 1383(a)(2), 1395d(a)(1), 1395f(a)-(b), 1395x(u). Although there may be differences in the manner in which beneficiaries become entitled to receive that payment, *see* 75 Fed. Reg. at 50,280-81, that is irrelevant to whether a patient is entitled to benefits under either program for particular patient days. As Judge Kavanaugh has observed, "[t]he only thing that unifies the government's inconsistent definitions of this term is its apparent policy of paying out as little money as possible." *See Northeast Hosp.*, 657 F.3d at 20 n.1 (Kavanaugh, J., concurring).

renders the agency's statutory interpretation wholly impermissible. *See Air Line Pilots*, 3 F.3d at 453 ("[A]n interpretation of the [statute] which is internally inconsistent [is] therefore unreasonable and impermissible under *Chevron*.").

As for the other issues that demanded consideration in the rulemaking, the government stretches to argue that it addressed the "key question in determining congressional intent," and shrugs off its failure to address financial implications with the breezy claim that the agency could not possibly have known of the severe impact on DSH hospitals. Gov. Br. 43-45. Neither argument succeeds.

The agency failed to provide any explanation, let alone "a satisfactory explanation," why its interpretation serves Congress's goals. *See Bell Atl. Tel. Cos. v. FCC*, 206 F.3d 1, 9 (D.C. Cir. 2000). The government first recounts the rule's restatement of some of the comments. *See* Gov. Br. 41. But a restatement of comments does not an explanation make. The government then notes the agency's one, purportedly explanatory line:

> Although there are differences between the status of these beneficiaries and those in the traditional fee-for-service program, we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A.

69 Fed. Reg. at 49,099; *see* Gov. Br. 41-42. But this is no explanation at all. The government's counsel now claims that the Secretary explained that part C patients are entitled to part A benefits in "the relevant sense," Gov. Br. 44, but the Secretary—who did not even use the term "relevant sense"—did not explain in

what sense part C beneficiaries are entitled to part A benefits or how their entitlement in that "sense" was "relevant" to anything having to do with the purpose of the DSH statute.[14] To the extent that this is any rationale at all, it is at best a "makeweight[]" rationale, with "no attempt to relate [it] to the goals that the Congress intended" the DSH statute to serve. *Athens Cmty. Hosp.*, 21 F.3d at 1179. That falls short of the "reasonable, albeit brief" explanation required. *Long Island Care at Home v. Coke*, 551 U.S. 158, 175 (2007) (upholding interpretation explaining why it was more consistent both with particular statutory terms and with "prior practices concerning other similarly worded exemptions").

The other explanation given by the government—that the part A/SSI fraction was intended to count low-income Medicare patients, while the Medicaid fraction was intended to count low-income non-Medicare patients is nowhere to be found in the rule, so it cannot supply the reasoned explanation that the Secretary did not

[14] Nor did the Secretary explain how entitlement in this unexplained "sense" was relevant to the DSH payment under section 1395ww(d)(5)(F) but not to the then-longstanding interpretation of the exact same "entitled" phrase for purposes of the immediately adjacent subparagraph (G). 42 U.S.C. § 1395ww(d)(5)(G); 55 Fed. Reg. 35,990, 35,996 (Sept. 4, 1990) (including only days for which patients are "entitled to payment under part A" within days "entitled to benefits under part A" even when patient remained eligible for and enrolled in part A). Although the Secretary subsequently changed her interpretation of this provision, 75 Fed. Reg. at 50,287, and this payment adjustment sunsets on October 1, 2013, the agency's failure to address its longstanding interpretation equating entitled to part A with payment under part A demonstrates the agency's lack of reasoned decisionmaking.

give. *Village of Barrington*, 636 F.3d at 660. Moreover, as discussed below, it is also just wrong.

In addition, although adverting to "differences" between part A and part C patients, 69 Fed. Reg. at 49,099, the agency did not explain them. One key difference, wholly unaddressed by the Secretary and relating directly to financial impact, is that part C beneficiaries "are less likely to qualify for SSI benefits than non-[part C] enrollees," so the 2004 change necessarily had the effect of "diluting the fraction" and significantly "decreas[ing] the DSH adjustment" payments. *Northeast Hosp.*, 657 F.3d at 5.

In short, the 2004 rule "cross[ed] the line from the tolerably terse to the intolerably mute." *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d 1112, 1120 (D.C. Cir. 2010). The non-explanation that part C beneficiaries and part A beneficiaries are different in some (unexplained) ways but part C beneficiaries are also in some (unexplained) sense still entitled to part A benefits cannot save the rule.

B. The Secretary's Revised Statutory Interpretation Is Unreasonable Under *Chevron* Because It Is Inconsistent With Congressional Intent

The 2004 rule must also be found impermissible under *Chevron* step two because it "conflict[s] with the policy judgments that undergird the statutory scheme," *Health Ins. Ass'n of Am.*, 23 F.3d at 416. Reasonableness is a function of

the interpretation's "conformity to statutory purposes" as well as its fit with the text. *Goldstein*, 451 F.3d at 880-881 ("[E]ven if the Advisers Act does not foreclose the Commission's interpretation, the interpretation falls outside the bounds of reasonableness."); *AFL-CIO v. Chao*, 409 F.3d 377 (D.C. Cir. 2005) (invalidating, under *Chevron* step two, an agency rule as inconsistent with congressional policy).

The government's defense of the reasonableness of its statutory interpretation rests on the incorrect premise that this Court has already decided the question. *See* Gov. Br. 22-23. But, as the government acknowledges, Gov. Br. 22, the only decision of this Court to have addressed the agency's policy reversal with respect to part C days, *Northeast Hospital*, expressly reserved the question of "whether the agency's interpretation of the statute is reasonable" at *Chevron* step two, 657 F.3d at 13, though Judge Kavanaugh would have found the agency's new rule invalid under *Chevron* step one and step two, *id*. at 23 n.4. The other case relied upon by the government, *Catholic Health Initiatives-Iowa*, is no help because it did not address the government's policy with respect to part C days at all, much less the government's flawed decisionmaking in the 2004 rule on that point. *See* 2013 WL 2476896, at *5. In short, neither of those cases addressed whether the 2004 rule reasonably interpreted "entitled to benefits under part A," 42

U.S.C. § 1395ww(d)(5)(F)(vi), to mean "entitled to Medicare Part A (or Medicare Advantage (Part C))," 42 C.F.R. § 412.106(b)(2)(iii)(B) (2007).

Considered on its merits, the interpretation embodied in the 2004 rule frustrates, rather than furthers, the purpose of the DSH adjustment. The government's brief suggests that the new rule furthers congressional intent that the part A/SSI fraction "serve as a proxy for the percentage of low-income *Medicare* patients," while the "Medicaid fraction was intended to serve as a proxy for low-income *non-Medicare* patients." Gov. Br. 44. This *post hoc* explanation is flatly incorrect and contradicts the Secretary's own interpretation of the part A/SSI fraction. Consistent with the intent of the DSH statute, the Secretary interprets that fraction to include not all "Medicare patients," but only Medicare *part A* patient days in areas of a hospital that are paid under the part A prospective payment system.

The purpose of the DSH adjustment is to provide additional payments under the part A prospective payment system for hospitals that incur higher costs in treating low-income patients. *See* H.R. Rep. No. 99-241(I), at 15 *reprinted in* 1986 U.S.C.C.A.N. 579, 593-94. This payment adjustment applies only to payments made under part A, for services furnished in areas of the hospital subject to part A, on behalf of patients who are entitled to have part A payments made on their behalf. *See* 42 U.S.C. § 1395ww(d)(5)(F); 42 C.F.R. § 412.106. To further this

purpose, the part A/SSI fraction serves as a proxy measure of the proportion of a hospital's total Medicare part A prospective payment system patient days attributable to individuals who are low-income and, therefore, more costly-than-average to treat. The part A/SSI fraction increases part A payments to account for the higher costs of treating low-income *part A* patients; it makes no sense to adjust that fraction by reference to part C patients whose care is not paid for under the part A prospective payment system. Because part C patient days are indisputably not paid under the part A prospective payment system, they should not be included either in the denominator or in the numerator of the part A/SSI fraction.

Indeed, the Secretary's own policy and practice reflect this same understanding of statutory purpose, rather than government counsel's view. Even under her current policy, the Secretary does not count all "Medicare beneficiaries" in the part A/SSI fraction. Nor does the Secretary even count all patient days for patients who are entitled to benefits under part A. The Secretary construes the part A/SSI fraction to include only days of patients in *areas* of a hospital that furnish services that are *payable* under the part A prospective payment system; any "part A" patient days in other areas of a hospital are excluded. *See* 42 C.F.R. § 412.106(a)(1)(ii) (2010) (excluding patient days in areas of a hospital that are not *paid* under the part A prospective payment system). Even within the prospective payment areas of a hospital, not all Medicare beneficiary patient days are counted

in the part A/SSI fraction. The agency has always excluded patient days for individuals who are enrolled only in part B. Questions and Answers Related to Program Memorandum A-99-62 (Mar. 13, 2000), Q3; JA-. And, she has determined that hospice patient days for part A beneficiaries should be excluded from the part A/SSI fraction because hospice services are not payable under the part A prospective payment system. 76 Fed. Reg. 51,476, 51,681-683 (Aug. 18, 2011).

Moreover, in adopting and clarifying these policies, the Secretary has relied on the very same legislative history the Hospitals rely on here. *See* 68 Fed. Reg. at 45,418 (citing the legislative history of the DSH statute in H.R. Rep. 99-241(I) in support of the Secretary's policy to limit the DSH calculation to patient days in areas of the hospital that provide services that are *paid* under the part A prospective payment system).

Given the inconsistency of the part C policy with the agency's own interpretation of the congressional intent of the part A/SSI fraction to be limited to days paid under the part A prospective payment system, the government does not come close to demonstrating "conformity to statutory purposes," which is necessary for an interpretation to pass muster under *Chevron* step two. *Goldstein*, 451 F.3d at 881.

V. THE DISTRICT COURT PROPERLY VACATED THE RULE AND ORDERED RECALCULATION OF THE HOSPITALS' REIMBURSEMENTS

The district court's vacatur and recalculation order was proper. Vacatur is the standard remedy for invalid agency action, even when the error is the failure to provide a reasonable explanation for a rule. Vacatur restores the prior rule excluding part C days from the part A/SSI fraction, especially given the Medicare statute's explicit requirement for this cure. The agency can implement its new policy under an amended rule only after undertaking a fresh notice and comment process.

First, vacatur is the proper remedy under the APA. The government concedes as much with respect to the failure to provide for adequate notice and comment, but contends incorrectly that remand *without* vacatur is warranted if the Court finds only that the government fails *Chevron* step two. *See* Gov. Br. 46-47. But any "unsupported agency action normally warrants vacatur." *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005). There is no exception when the agency has adopted a statutory interpretation that is unreasonable under *Chevron*. *See, e.g.*, *Northpoint*, 412 F.3d at 156 (vacating agency action adopting unreasonable statutory interpretation under *Chevron*); *AFL-CIO*, 409 F.3d at 391 (same); *Bell Atl. Tel. Cos.*, 206 F.3d at 9 (same).

Rules may be vacated "even when [this Court] ha[s] not foreclose[d] the possibility that the [agency] may develop a convincing rationale for re-adopting the same rule on remand." *Illinois Pub. Telecomms. Ass'n v. FCC*, 123 F.3d 693, 694 (D.C. Cir. 1997) (on motion for clarification). And here, the agency's utter failure to explain its policy reversal mandates vacatur. *Heartland Reg. Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) ("[W]hen an agency's explanation of the basis and purpose of its rule is so inadequate that the reviewing court cannot evaluate it, the regulation is subject to vacatur under the first *Allied-Signal* factor."). Vacatur is particularly warranted because the government's failure forthrightly to acknowledge and explain its departure from long-standing prior policy infected and undercut the reasonableness of the entire decisionmaking process. This Court has recognized that an agency is unlikely to "seriously consider [comments] after the regulations are a *fait accompli*." *New Jersey, Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1049-50 (D.C. Cir. 1980). Because the agency's failure to explain its past policy deprived it of the benefit of parties' informed "expertise and input" at the formative stage of the decision-making process, when the agency still has a "flexible and open minded attitude toward its own rules," *Nat'l Tour Brokers Ass'n*, 591 F.2d at 902, a new rulemaking is warranted.

Second, the required recalculation of the Hospitals' payments is proper because vacatur of a rule adopting a policy change restores the previously-governing policy until it is changed by a valid rulemaking. *See Croplife Am. v. EPA*, 329 F.3d 876, 879 (D.C. Cir. 2003) (vacating rule and holding that "[a]s a consequence, the agency's previous practice ... is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation"); *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 797-98 (D.C. Cir. 1983) ("[B]y vacating or rescinding [one rule], the judgment of this court had the effect of reinstating the rules previously in force," which "cannot again be revoked without new rulemaking[.]"). Because the prior policy continues in effect, any change to that policy, through a new, valid rulemaking, necessarily cannot be retroactively applied. *See Arkema*, 618 F.3d at 7.

The government's assumption is that vacatur returns it to a status quo ante of *no* policy, such that notice and comment rulemaking is not required to make a change. Gov. Br. 48-49. But that is, yet again, simply re-fighting the fight the government has already lost in *Northeast Hospital*, 657 F.3d at 14-17. In *Northeast Hospital*, this Court concluded that the agency in 2004 "changed its interpretation" of the phrase "entitled to benefits under part A," which previously had been interpreted to mean "covered," *i.e.*, paid, under part A. *Id.* at 16; *see* 42 C.F.R. § 412.106(b)(2) (2003). Accordingly, the agency may not change its

interpretation without notice and comment. *See Envtl. Integrity Project*, 425 F.3d at 995 ("[A]n interpretation of a legislative rule cannot be modified without the notice and comment procedure that would be required to change the underlying regulation—otherwise, an agency could easily evade notice and comment requirements by amending a rule under the guise of reinterpreting it."); *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997)

Moreover, in relying on *Catholic Health Initiatives-Iowa* to support the application of the new policy to the periods at issue here, the government ignores what the Court explicitly noted in *Catholic Health Initiatives* about the part A/SSI fraction. Namely, the Court highlighted the agency's pre-2004 policy regarding the Medicare part A/SSI fraction to include only days covered, or paid, by Part A, which was long-standing and embodied in a legislative rule that binds the agency. *See* 2013 WL 2476896, at *6 n.5. The agency may not "effectively repeal" that prior rule and "abandon longstanding interpretations of statutes indirectly, by adjudication"—even prospectively. *Am. Fed'n of Gov't Emps. v. Fed. Labor Relations Auth.*, 777 F.2d 751, 759 (D.C. Cir. 1985); *see also Rainbow Navigation, Inc. v. Dep't of Navy*, 783 F.2d 1072, 1080 (D.C. Cir. 1986); *Action on Smoking & Health*, 713 F.2d at 798.

Nor does the first *Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005), help the government. That case did *not* address a rule that had

reversed a prior, long-standing rule interpreting the statute. *See Heartland Reg'l*, 415 F.3d at 26 (addressing invalidation of a rule that was the agency promulgation of a standard for determining sole community hospital status).

Finally, the government fails to account for a unique provision of the Medicare statute, which expressly requires that the invalid rule "shall not take effect" until properly promulgated with notice and comment, 42 U.S.C. § 1395hh(a)(4), and that the agency cannot "change[] a substantive legal standard governing … the payment for services," until the change is promulgated by proper rulemaking, *id.* § 1395hh(a)(2). These statutory proscriptions do not afford the agency the option of going forward as if its vacated rule continued to be in force. The district court's recognition that a new future rulemaking was required, and that it would necessarily result in a rule that could not retroactively be applied to the 2007 cost years at issue, resulted in an entirely proper order to recalculate the part A/SSI fractions under the prior policy that the Secretary never validly changed.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing brief is in 14-point Times New Roman proportional font and contains 13,992 words, and thus complies with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

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August 1, 2013

CERTIFICATE OF SERVICE

I hereby certify that, on August 1, 2013, I served the foregoing brief upon the following counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system:

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ADDENDUM

TABLE OF CONTENTS

United States Code

Title 42. The Public Health and Welfare

Chapter 7. Social Security

Subchapter XVIII. Health Insurance for Aged and Disabled

Part E. Miscellaneous Provisions

§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

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(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

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United States Code

Title 42. The Public Health and Welfare

Chapter 7. Social Security

Subchapter XVIII. Health Insurance for Aged and Disabled

Part E. Miscellaneous Provisions

§ 1395ww. Payments to hospitals for inpatient hospital services

*****

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographic Classification Review Board

*****

(5)(F)

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(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of-

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, but who were not entitled to

benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

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2013 Code of Federal Regulations

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B. Medicare Program

Part 412. Prospective Payment Systems for Inpatient Hospital Services

Subpart G. Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Costs

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

*****

(b) *Determination of a hospital's disproportionate patient percentage*--(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year*. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS--

(i) Determines the number of patient days that--

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that--

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period*. If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation*. The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(iv) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the

second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written notification must specify the methodology the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

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2008 Code of Federal Regulations

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B. Medicare Program

Part 412. Prospective Payment Systems for Inpatient Hospital Services

Subpart G. Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Costs

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

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(b) *Determination of a hospital's disproportionate patient percentage*--(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year*. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS--

(i) Determines the number of patient days that--

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (or Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that--

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (or Medicare Advantage (Part C)).

(3) *First computation*: *Cost reporting period*. If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation*. The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this

section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

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2003 Code of Federal Regulations

Title 42. Public Health

Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services

Subchapter B. Medicare Program

Part 412. Prospective Payment Systems for Inpatient Hospital Services

Subpart G. Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Costs

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

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(b) *Determination of a hospital's disproportionate patient percentage*. (1) *General rule*. A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year*. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS --

(i) Determines the number of covered patient days that --

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that --

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period*. If a hospital prefers that HCFA use its cost reporting period instead of the Federal fiscal year, it must furnish to HCFA, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation*. The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section

and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405, 412, and 489

[BERC-385-IFC]

Medicare Program; Fiscal Year 1986 Changes to the Inpatient Hospital Prospective Payment System

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule sets forth revisions to the Medicare inpatient hospital prospective payment system. This rule is needed to implement those portions of sections 9101 through 9105 and 9112 of the Consolidated Omnibus Budget Reconciliation Act of 1985 having an effective date of May 1, 1986 or earlier. The changes required by this legislation affect the fiscal year 1986 prospective payment rates; the rate-of-increase limits (target amounts) for hospitals excluded from the prospective payment system; the length of the transition period and the method of payment; application of the hospital wage index; payment for the indirect costs of medical education; and payments for hospitals that serve a disproportionate share of low-income patients.

DATES: Effective date: With certain exceptions, this interim final rule is effective on May 1, 1986. We refer the reader to section VII.B. of this preamble for a detailed discussion of effective dates.

Comment Date: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on June 5, 1986.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-385-IFC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-285-IFC. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT: Linda Magno, (301) 594-9343.

SUPPLEMENTARY INFORMATION:

I. Background

On September 3, 1985, we published a final rule in the **Federal Register** (50 FR 35646) that made the following changes to the Medicare inpatient hospital prospective payment system:

- We adjusted the diagnosis-related groups (DRG) classifications and weighting factors for discharges occurring on or after October 1, 1985.
- For cost reporting periods beginning on or after October 1, 1983, we adopted a new hospital wage index that was based on the HCFA survey of hospital wages.
- We made several changes to the regulations in 42 CFR Parts 405 and 412 concerning—

—The rate-of-increase limits for hospitals excluded from the prospective payment system;
—Payments for indirect costs of medical education;
—Limitations on charges to beneficiaries for hospitals paid under State reimbursement control systems or demonstration projects;
—The exclusion of alcohol/drug hospitals and units;
—Review of cost outliers; and
—Qualifying criteria for referral centers.

- We established the FY 1986 Federal rates by—

—Restandardizing the base year cost data to reflect the new wage index;
—Grouping the standardized costs per case for urban/rural averages for the nine census regions and the nation, reflecting the most recent geopgraphic designations;
—Updating the standardized amounts by zero percent; and
—Applying the same adjustment factors for nonphysician anesthetist costs and outlier payments as were used for FY 1985.

- We did not increase either the hospital-specific rates for hospitals under the prospective payment system or the rate-of-increase limits for hospitals excluded from the prospective payment system.

With certain exceptions, the September 3 final rule was to be effective on October 1, 1985.

On September 30, 1985, the Emergency Extension Act of 1985 (Pub. L. 99-107) was enacted. Section 5 of Pub. L. 99-107 extended through November 14, 1985 the Medicare payment rates for inpatient hospital services that were in effect on September 30, 1985. A result of this delay was that certain changes in the rules that govern Medicare payment for inpatient hospital services, which would have become effective on October 1, 1985, for FY 1986 as a result of the September 3, 1985 final rule, were postponed initially until November 15, 1985. The affected changes concerned the rules for determining payment rates for hospitals covered by the prospective payment system and the rate-of-increase limits for hospitals excluded from that system. In addition, the amendments to 42 CFR 412.118(f)(2) and (f)(3) concerning determination of indirect medical education costs that were scheduled to be effective on October 1, 1985 under the September 3, 1985 final rule were also postponed until November 15, 1985. We announced this postponement in a notice in the **Federal Register** published on November 12, 1985 (50 FR 46651).

Since publication of that notice, several more laws were enacted that further delayed the implementation of revised Medicare inpatient hospital services payment rules as follows:

- Pub. L. 99-155, enacted December 14, 1985, extended the delay through December 14, 1985.
- Pub. L. 99-181, enacted December 13, 1985, extended the delay through December 18, 1985.
- Pub. L. 99-189, enacted December 18, 1985, extended the delay through December 19, 1985.
- Pub. L. 99-201 enacted December 23, 1985, extended the delay through March 14, 1986.

To announce the first of these extensions of the delay, we published a notice in the **Federal Register**, on December 6, 1985 (50 FR 49930); the remaining extensions were described in a notice published February 3, 1986 (51 FR 4166). The result of these extensions is that, for the period of the extension, we continued to pay for hospital discharges under the rules that were in effect in FY 1985. Thus, we did not implement the following changes that were included in the September 3, 1985 final rule:

- Revised DRG classifications and weights.
- Revised wage index.
- Revised adjusted standardized amounts.
- Revised regulations concerning exclusions on the count of interns and

G. Subpart G is amended as follows:

Subpart G—Special Treatment of Certain Facilities

1. In § 412.90, a new paragraph (h) is added to read as follows:

§ 412.90 General rules.

* * * * *

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1, 1986 and before October 1, 1988, HCFA makes an additional payment to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

2. A new § 412.106 is added to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) *Basic rule.* (1) Unless a hospital elects the option concerning the period of time used for counting the number of patient days (that is, the hospital's cost reporting period rather than the Federal fiscal year), as described in paragraph (a)(2) of this section, a hospital's disproportionate patient percentage is the sum of the following, expressed as a percentage:

(i) Number of covered patient days during each month of the Federal fiscal year in which the hospital's cost reporting period begins of those patients who are entitled during that month to both Medicare Part A and Supplemental Security Income benefits under title XVI of the Act (excluding those patients receiving State supplementation only), summed for the months of the Federal fiscal year, and divided by the number of patient days during that same Federal fiscal year of those patients entitled to Medicare Part A.

(ii) Number of patient days during the hospital's cost reporting period of those patients who are entitled to Medicaid but not to Medicare Part A divided by the total number of patient days in that same period.

(2) For purposes of making the calculation in paragraph (a)(1)(i) of this section, a hospital may elect to have the count of the number of patient days made on the basis of its cost reporting period, rather than by Federal fiscal year, if the following conditions are met:

(i) The hospital furnishes to its intermediary, in a manner and format prescribed by HCFA, data on its Medicare Part A patients for its cost reporting period.

(ii) The hospital bears the full cost of preparing its submittal as described in paragraph (a)(2)(i) of this paragraph and the cost incurred by SSA in determining the number of beneficiaries entitled to both Medicare Part A and Supplemental Security Income benefits for each month of the cost reporting period.

(3) The number of beds in a hospital is determined as specified in § 412.118(b).

(4) The definitions for urban and rural areas are the same as those set forth in § 412.62(f).

(6) *Criteria for classification.* For discharges occurring on or after May 1, 1986 and before October 1, 1988, a payment adjustment (as described in paragraph (c) of this section) is made for each hospital that meets one of the following criteria:

(1) During the hospital's cost reporting period, the hospital has a disproportionate patient percentage that is at least equal to—

(i) 15 percent, if the hospital is located in an urban area and has 100 or more beds;

(ii) 40 percent, if the hospital is located in an urban area and has fewer than 100 beds; or

(iii) 45 percent, if the hospital is located in a rural area.

(2) The hospital is located in an urban area, has 100 or more beds, and can demonstrate that, during its cost reporting period, more than 30 percent of its total inpatient care revenues are derived from State and local government payments for indigent care furnished to patients who are not covered by Medicare or Medicaid.

(c) *Payment adjustment.* If a hospital meets one of the criteria in paragraph (b) of this section, the hospital's total DRG revenue based on DRG–adjusted prospective payment rates (for transition period payments, the Federal portion of the hospital's payment rates), including outlier payments determined under Subpart F of this part but excluding additional payments made under the provisions of this subpart or § 412.118, is increased by the disproportionate share payment adjustment factor, determined as follows:

(1) If the hospital meets the criteria of paragraph (b)(1) (i) of this section, the disproportionate share payment adjustment factor is the lesser of—

(i) 15 percent; or

(ii) 2.5 percent plus one-half the difference between the hospital's disproportionate patient percentage and 15 percent.

(2) If the hospital meets the criteria of paragraph (b)(1)(ii) of this section, the disproportionate share payment adjustment factor is five percent.

(3) If the hospital meets the criteria of paragraph (b)(1)(iii) of this section, the disproportionate share payment adjustment factor is four percent.

(4) If the hospital meets the criteria of paragraph (b)(2) of this section, the disproportionate share payment adjustment factor is 15 percent.

F. Subpart H is amended as follows:

Subpart H—Payments to Hospitals under the Prospective Payment System

§ 412.113 [Amended]

1. In § 412.113, paragraph (b) is amended by revising the date in the third sentence from "Ootober 1, 1986" to "October 1, 1987".

2. Section 412.118 is amended by revising the introductory language; revising paragraphs (a) and (c); redesignating current paragraphs (d), (e), (f), and (g) as paragraphs (e), (f), (g), and (h), respectively; adding a new paragraph (d); and revising newly redesignated paragraphs (e) and (g) to read as follows:

§ 412.118 Determination of indirect medical education costs.

To determine the indirect medical education costs, HCFA uses the following procedures:

(a) *Basic data.* HCFA determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent interns and residents, except as limited under paragraph (g) of this section, to number of beds (as determined in paragraph (b) of this section).

(2) The hospital's total DRG revenue based on DRG-adjusted prospective payment rates (for transition period payments, the Federal portion of the hospital's payment rates), including outlier payments determined under Subpart F of this part but excluding additional payments made under the provisions of Subpart G of this Part. For cost reporting periods beginning on or after January 1, 1986, for purposes of this section, the total DRG revenue is not offset for payments made to outside suppliers under § 489.23 of this chapter for nonphysician services furnished to beneficiaries entitled to Medicare Part A.

* * * * *

(c) *Measurement for teaching activity.* The factor representing the effect of teaching activity on inpatient operating costs is equal to the following:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 412

[BERC-353-F]

Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1987 Rates

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: We are amending the Medicare regulations governing the inpatient hospital prospective payment system to implement necessary changes arising from legislation and our continuing experience with the system.

In addition, we are describing changes in the methods, amounts, and factors necessary to determine prospective payment rates for Medicare inpatient hospital services. In general, these changes are applicable to discharges occurring on or after October 1, 1986. We are also setting forth the update factor for determining the rate-of-increase limits (target amounts) for hospitals excluded from the prospective payment system.

EFFECTIVE DATE: This final rule is effective on October 1, 1986. We refer the reader to section VI.A. of this preamble for a discussion of specific provisions that apply to specific periods.

FOR FURTHER INFORMATION CONTACT: Linda Magno, (301) 594-9343.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of the Implementation of the Prospective Payment System

Under section 1886(d) of the Social Security Act (the Act), enacted by the Social Security Amendments of 1983 (Pub. L. 98-21) on April 20, 1983, a prospective payment system for Medicare payment of inpatient hospital services was established effective with hospital cost reporting periods beginning on or after October 1, 1983. Under this system, Medicare payment is made at a predetermined, specific rate for each discharge. All discharges are classified according to a list of diagnosis-related groups (DRGs).

We published an interim final rule in the **Federal Register** (48 FR 39752) on September 1, 1983 to implement the prospective payment system effective with hospital cost reporting periods beginning on or after October 1, 1983. Technical corrections for that rule were issued on October 19, 1983 (48 FR 48467).

On January 3, 1984, we issued a final rule (49 FR 234) to make changes resulting from our consideration of public comments that were received in response to the interim final rule. Technical corrections for that rule were issued on June 1, 1984 (49 FR 23010).

As a result of our first year of experience with the prospective payment system and to accommodate changes resulting from the enactment of the Deficit Reduction Act of 1984 (Pub. L. 98-369) on July 18, 1984, we published a final rule on August 31, 1984 (49 FR 34728) that further revised the prospective payment regulations. In addition, we made changes in the methods, amounts, and factors necessary to implement the second year of the transition period. Technical corrections for that final rule were issued on October 15, 1984 (49 FR 40167).

On March 29, 1985, we published a final rule (50 FR 12740) that redesignated the prospective payment regulations under a new 42 CFR Part 412. These regulations were previously located in 42 CFR 405.470 through 405.477.

Taking into consideration the recommendations made by the Prospective Payment Assessment Commission (PROPAC) under the authority of section 1886(d)(4)(D) of the Act, we published a final rule on September 3, 1985 (50 FR 35646) to implement the third year of the transition period. Technical corrections for that final rule were issued on October 28, 1985 (50 FR 43570). However, beginning on September 30, 1985, Congress enacted a series of statutory extensions of the hospital payment rates that were in effect on September 30, 1985. The effect was to delay implementation of the September 3, 1985 final rule with the result that the revised payment rates for hospitals covered by the prospective payment system and the rate-of-increase limits for hospitals excluded from that system, which were originally scheduled to be effective on October 1, 1985, were postponed through April 30, 1986. We notified the public about these extensions (50 FR 46651 and 49930, and 51 FR 4166) and, after the President signed the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99-272) into law on April 7, 1986, we issued an interim final rule with comment period on May 6, 1986 (51 FR 16772). That rule implemented new Federal fiscal year (FY) 1986 hospital payment rates effective for discharges occurring on or after May 1, 1986 for prospective payment hospitals and for cost reporting periods beginning on or after October 1, 1985 for hospitals excluded from the prospective payment system.

The comment period for the interim final rule ended on June 5, 1986. We are responding to the comments received on that rule in section II of this preamble. Certain clarifying changes to the regulations, in response to the comments received on the interim final rule, are set forth in this document.

B. Summary of June 3, 1986 Proposed Rule

On June 3, 1986, we published a notice of proposed rulemaking (NPRM or proposed rule) in the **Federal Register** (51 FR 19970) to further amend the prospective payment system. We proposed to make the following changes:

- Under section 1886(a)(4) of the Act, we proposed to incorporate capital-related costs into the prospective payment system effective with cost reporting periods beginning in FY 1987. However, on July 2, 1986, Pub. L. 99-349 was enacted and included a provision (section 206) that amended section 1886(a)(4) of the Act to extend the period (through cost reporting periods beginning prior to October 1, 1987) during which capital-related costs must be treated separately from other inpatient hospital operating costs. Therefore, we are not incorporating capital-related costs into the prospective payment system in this final rule. Accordingly, we are not addressing in this final rule the comments we received concerning that proposal. However, we will consider the comments as we deliberate this matter further.
- We proposed to recompute the hospital market basket using data from a more recent base year (that is, "rebasing" the market basket) and to recalculate the weights of each of the components of the hospital market basket (that is, "reweighting" the market basket cost categories).
- We discussed several decisions and current provisions of the regulations in 42 CFR Parts 405 and 412, and set forth proposed changes concerning—

—Establishment of a base period for hospitals newly subject to the rate-of-increase ceiling;

—Extension of the exclusion for excluded alcohol/drug hospitals and units from the prospective payment system;

—Hospitals in redesignated rural counties which are surrounded on all sides by urban counties;

—Changes to referral center criteria; and

—Changes to the DRG classification system.

These results indicate a high degree of correlation between SSI/Medicare percentages computed based on the Federal fiscal year and those computed by hospital cost reporting period. (A coefficient of 1.0 equals a perfect correlation.)

In addition, we also point out that for a significant proportion of hospitals within each of these groups, the SSI/Medicare ratio computed for Federal FY 1984 was within 2.3 percentage points (approximately one standard deviation of the mean difference) of the actual value derived from the hospital's own cost reporting period that began in Federal FY 1984, as shown below:

Disproportionate share groups	Percentage [1]
Urban—100 or more beds	95.5
Urban—less than 100 beds	81.4
Rural	80.5
Overall	86.9

[1] Percentage of hospitals whose SSI/Medicare ratio for Federal fiscal year 1984 is within .023 of the SSI/Medicare ratio for its cost reporting period beginning in Federal fiscal year 1984.

While the variability in the percentages is somewhat higher for the small urban hospital and rural hospital groups, generally only those hospitals in these two groups with overall disproportionate patient percentages that fall short by a small margin of meeting the necessary thresholds to qualify for an adjustment (that is, 40 percent and 45 percent, respectively) could be impacted. This is because the amount of the disproportionate share adjustment for qualifying hospitals in these two groups is not dependent on the amount of their disproportionate patient percentages.

We do not believe Congress intended to impose such a cumbersome and costly administrative burden as that described above in implementing this provision. The Secretary has general rulemaking authority under section 1102 and 1871 of the Act to deal with problems of implementing and administering the Act in an efficient manner. Based on the above discussion, we believe that using the Federal fiscal year instead of a hospital's own cost reporting period is the most feasible approach to implementing this provision in terms of accuracy, timeliness and cost efficiency. In addition, we believe we have complied with the law by affording hospitals the option of having their SSI/Medicare percentage computed based on its own cost reporting period.

Comment: Several commenters objected to our definition of Medicaid patient days for purposes of computing a hospital's disproportionate patient percentage. These commenters stated that all inpatient days associated with a Medicaid recipient should be counted whether or not the patient was actually covered by Medicaid for those days. These commenters focused on the term "patients who . . . were eligible for medical assistance . . ." in section 1886(d)(5)(F)(vi)(II) of the Act and argued that, since a patient would still be "eligible" for Medicaid benefits even though part or all of the patient's care may not be covered by Medicaid for a certain day, all patient days for which care was actually provided to a Medicaid eligible individual should be counted.

Response: We believe that the parenthetical phrase "for such days" in section 1886(d)(5)(F)(vi)(II) of the Act was intended to modify the phrase "eligible for medical assistance" and that Congress intended to include only such patient days for which the Medicaid patient was eligible to have his or her care paid for by the Medicaid program. We believe evidence of Congressional intent in this regard may be found in the legislative history of section 1886(d)(5)(F)(vi) of the Act.

The Conference Report described the House bill on section 9105 of Pub. L. 99-272 as defining low income patients as follows:

> The proxy measure for low income would be the percentage of a hospital's total inpatient days attributable to medicaid patients (including medicaid-eligible medicare beneficiaries—medicare/medicaid crossovers).

(See H.R. Rep. No. 99–453, 99th Cong., 1st Sess. 459 (1985).) The phrase "inpatient days attributable to medicaid patients" supports the commenters' interpretation that all days that are attributable to Medicaid patients (that is, for which the patient is Medicaid-eligible) must be included in the numerator of the definition. However, the House bill's definition was not ultimately accepted by the Conference Committee. The Conference Report states that:

> The percentage of low income patients will be defined as the total number of inpatient days attributable to Federal Supplemental Security Income beneficiaries divided by the total number of medicare patient days, plus the number of *medicaid patient days* divided by total patient days. (Emphasis added.)

(See H.R. Rep. No. 99–453, 99th Cong., 1st Sess. 461 (1985).) The substitution of the term "number of medicaid patient days" in the Conference agreement for the previous term "attributable to medicaid patients" suggests that Congress intended to adopt the definition as we currently understand it (that is, only hospital days covered by Medicaid should be included in the numerator.) We believe that Congress consciously changed the focus of the Medicaid definition from the number of days that may be attributable to individuals eligible for Medicaid to the actual "number of Medicaid patient days" (that is, days that were paid for by the State's Medicaid program).

We believe this interpretation, that only Medicaid covered days should be counted, is not inconsistent with the statutory scheme as a whole, since the formula in section 1886(d)(5)(F)(vi) of the Act does not purport to identify all indigent patients. Rather, it refers to certain Medicare and Medicaid patients as an easily and objectively determined proxy for the indigent. Thus, under any reading of the statute, not all indigent patients are included in the formula. A Medicaid eligible recipient who has exhausted his or her benefits is thus situated similarly to the indigent patient who is not eligible for Medicaid at all, and so it is logical to treat them the same for purposes of determining the disproportionate patient percentage.

In addition, given the relatively short timeframe for implementing section 1886(d)(5)(F)(vi) of the Act, we believe it is reasonable to assume that Congress anticipated that the Medicare cost report would serve as the primary source for Medicaid patient day statistics. Our definition of Medicaid patient days is consistent with the way we require Medicaid days to be reported on the Medicare cost report. On that form, a day of care is designated a Medicaid patient day only if the Medicaid program is the primary payor. There is no provision on the form for a patient day being counted as more than one type for payment purposes. We do not believe that Congress intended that an additional reporting mechanism, possibly tied to State eligibility records, be developed to obtain Medicaid statistics on noncovered patient days.

Therefore, since Congress clearly intended that the disproportionate share adjustment be implemented promptly with the data currently available, we believe the definition of Medicaid patient days published in the interim final rule is the one that Congress intended that we adopt.

We should also point out that our interpretation that the Medicaid portion of the definition of the disproportionate share percentage under section 1886(d)(5)(F)(vi)(II) of the Act refers only to Medicaid covered days is consistent with our interpretation of the Medicare portion under section 1886(d)(5)(F)(vi)(I) of the Act, (which uses similar language)

to refer only to Medicare covered days. In the preamble to the interim final rule, we indicated that we would count "covered" Medicare days in determining the Medicare portion of a hospital's disproportionate patient percentage. However, we received no comments on this issue.

D. Other Comments

Comment: One commenter believes that a 30-day comment period does not provide enough time for the public to comment on rule changes to a program as important as the prospective payment system. The commenter would prefer a 60-day comment period. In addition, the commenter is concerned that comments are considered only if they are received by HCFA by the end of the indicated comment period. Since commenters have no control over the date a comment is received, HCFA should consider all comments postmarked by the end of the comment period.

Response: It was important that we move quickly to inform the public as soon as possible about the provisions of Pub. L. 99–272 that affected implementation of the prospective payment system during FY 1986. Congress authorized issuance of an interim final rule (section 9115(b) of Pub. L. 99–272), and mandated the effective date of the provisions dealt with in the interim final rule. In addition, under section 1886(e)(5)(B) of the Act, we were required to issue the proposed update for the prospective payment system for FY 1987 by June 1, 1986 and the final rule by September 1, 1986.

As indicated in section I of this preamble, this leaves no time for a comment period of longer than 30 days on the proposed updates. Therefore, in order to deal with the comments on the Pub. L. 99–272 interim final rule and the proposed FY 1987 update in an organized sequential manner, we established the 30-day comment period for the interim final rule. A 60-day comment period would have meant that the comment periods for both the interim final rule and the proposed FY 1987 update would have ended virtually simultaneously. This in turn would have meant that we would have been required to address comments on both documents at the same time, thereby complicating the process of meeting the September 1, 1986 statutory deadline for publication of the FY 1987 final rule.

As discussed above, we normally provide a 60-day comment period if circumstances permit it. However, given the need to issue regulations to implement Pub. L. 99–272 quickly combined with the imminent publication of the FY 1987 prospective payment proposal, we determined that a 30-day comment period was necessary. We also point out that, for the most part, those provisions in Pub. L. 99–272 affecting the prospective payment system in FY 1986 were ones about which we had little administrative discretion concerning their substance or implementation. Therefore, a longer public comment period for those provisions would have been unnecessary. In addition, although there is no specified minimum time for the length of a public comment period, the courts have consistently held that a 30-day comment period is sufficient.

With regard to how the comment period date is applied, we consider to be timely only those comments that are received by the last day of the comment period rather than those postmarked by the last day of the comment period because postmarks are not always a reliable indicator of when a comment was sent. In many cases, the postmark is illegible and thus cannot be used to prove when a comment was sent. Also, for those commenters who use a postal meter outside the post office, a meter may be changed to reflect a date other than the one on which the comment was actually sent, or a predated envelope may be used to send a late comment. Expedited mail services are available from the post office and from private carriers to help ensure that comments are delivered timely. We believe that our policy is not only reliable but equitable since it imposes the same constraints on all commenters.

Comment: One commenter requested that in all future documents concerning the prospective payment system that are published in the **Federal Register**, we should present a table of outlier criteria and thresholds that includes the labor portion percentage, national ratio of cost to charges, the fixed dollar minimum, and the minimum multiple of the Federal DRG rate.

Response: The outlier criteria and thresholds are routinely published in the **Federal Register** as a part of the proposed and final rules concerning the annual update to the prospective payment rates. This information was not published in the May 6, 1986 interim final rule implementing sections 9101 through 9105 and 9112 of Pub. L. 99–272 since the outlier criteria and thresholds for FY 1986 published in the **Federal Register** on September 3, 1985, were not changed as a result of this legislation. We did not see the necessity of republishing this information since we believe it was clearly understood that absent any specific changes made by Pub. L. 99–272, the changes to the prospective payment system that were published in the **Federal Register** on September 3, 1985 would become effective May 1, 1986.

III. Rebasing and Reweighting of the Hospital Market Basket

A. Background

For cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital "market basket") for use in establishing the limits on hospitals' routine operating costs (44 FR 31802). The percentage change in the market basket reflects the average change in the price of goods and services purchased by hospitals to furnish inpatient care. Traditionally, we used the market basket to adjust hospitals' cost limits by an amount that reflects the average increase in the prices of the goods and services used to furnish inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

With the inception of the prospective payment system on October 1, 1983, we continued to use the market basket to update each hospital's 1981 inpatient operating cost per discharge used in establishing the standardized payment amounts. In addition, the projected change in the market basket is one of the integral components of the update factor by which the prospective payment rates were updated for FY 1985. An explanation of the market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). For additional background information on the market basket index, we refer the reader to the article by Freeland, Anderson, and Schendler, "National Hospital Input Price Index," *Health Care Financing Review*, Summer 1979, pp. 37–61.

The market basket is a Laspeyres or fixed-weight price index constructed in two steps. First, a base period is selected and the proportion of total expenditures accounted for by designated spending categories is calculated. These proportions are called cost or expenditure weights. In the second step, a rate of increase for each spending category is multiplied by the expenditure weight for that category. The sum of these products for all cost categories yields the percentage change in the market basket, an estimate of price change for a fixed quantity of purchased goods and services.

The market basket is described as a fixed-weight index because it answers the question of how much more or less it would cost at a later time to purchase the same mix of goods and services that

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412 and 413

[CMS–1470–P]

RIN 0938–AL89

Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital costs to implement changes arising from our continuing experience with these systems. In addition, in the Addendum to this proposed rule, we are describing proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes would be applicable to discharges occurring on or after October 1, 2003. We also are setting forth proposed rate-of-increase limits as well as proposed policy changes for hospitals and hospital units excluded from the IPPS.

Among other changes that we are proposing are changes to the policies governing postacute care transfers, payments to hospitals for the direct and indirect costs of graduate medical education, determination of hospital beds and patient days for payment adjustment purposes, and payments to critical access hospitals (CAHs).

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on July 18, 2003.

ADDRESSES: Mail written comments (an original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1470–P, P.O. Box 8010, Baltimore, MD 21244–1850.

If you prefer, you may deliver, by hand or courier, your written comments (an original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters who wish to retain proof of filing by stamping in and keeping an extra copy of the comments being filed.)

Comments mailed to those addresses specified as appropriate for courier delivery may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1470–P.

For information on viewing public comments see the beginning of the **SUPPLEMENTARY INFORMATION** section.

For comments that relate to information collection requirements, mail a copy of comments to the following addresses:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Security and Standards Group, Office of Regulations Development and Issuances, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Attn: Julie Brown, CMS–1470–P; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

FOR FURTHER INFORMATION CONTACT:

Stephen Phillips, (410) 786–4548, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Patient Transfers, Counting Beds and Patient Days, and Hospital Geographic Reclassifications Issues;

Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Nursing and Allied Health Education, Graduate Medical Education, and Critical Access Hospital Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room C5–12–08 of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to schedule an appointment to view public comments.

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $10.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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Table of Contents

Medicaid fraction, even if the patient's Medicare Part A coverage has been exhausted. We believe this interpretation is consistent with the statutory intent of section 1886(d)(5)(F)(vi)(II) of the Act. However, we recognize there are other plausible interpretations. In addition, on a more practical level, we recognize it is often difficult for fiscal intermediaries to differentiate the days for dual-eligible patients whose Part A coverage has been exhausted. The degree of difficulty depends on the data provided by the States, which may vary from one State to the next. Some States identify all dual-eligible beneficiaries in their lists of Medicaid patient days provided to the hospitals, while in other States the fiscal intermediary must identify patient days attributable to dual-eligible beneficiaries by matching Medicare Part A bills with the list of Medicaid patients provided by the State. The latter case is problematic when Medicare Part A coverage is exhausted because no Medicare Part A bill may be submitted for these patients. Thus, the fiscal intermediary has no data by which to readily verify any adjustment for these cases in the Medicaid data provided by the hospital. Currently, the fiscal intermediaries are reliant on the hospitals to identify the days attributable to dual-eligible beneficiaries so these days can be excluded from the Medicaid patient days count.

Therefore, in order to facilitate consistent handling of these days across all hospitals, we are proposing that the days of patients who have exhausted their Medicare Part A coverage will no longer be included in the Medicare fraction. Instead, we are proposing these days should be included in the Medicaid fraction of the DSH calculation. (We note that not all SSI recipients are Medicaid eligible. Therefore, it will not be automatic that the patient days of SSI recipients will be counted in the Medicaid fraction when their Part a coverage expires.)

Under this proposed change, before a hospital could count patient days attributable to dual-eligible beneficiaries in the Medicaid fraction, the hospital must submit documentation to the fiscal intermediary that justifies including the days in the Medicaid fraction after the Medicare Part A benefits have been exhausted. That is, if the State provides data on all the days associated with all dual-eligible patients treated at a hospital, regardless of whether the beneficiary had Medicare Part A coverage, the hospital is responsible for providing documentation showing which days should be included in the Medicaid fraction because Medicare Part A coverage was exhausted.

8. Medicare+Choice (M+C) Days

Under § 422.1, an M+C plan ''means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.'' Generally, each M+C plan must provide coverage of all services that are covered by Medicare Part A and Part B (or just Part B if the M+C plan enrollee is only entitled to Part B).

We have received questions whether patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The question stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C.

We note that, under § 422.50, an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A.

Therefore, we are proposing to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. These patient days should be included in the count of total patient days in the Medicaid fraction (the denominator), and the patient's days for the M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction.

D. Medicare Geographic Classification Review Board (MGCRB) Reclassification Process (§ 412.230)

With the creation of the MGCRB, beginning in FY 1991, under section 1886(d)(10) of the Act, hospitals could request reclassification from one geographic location to another for the purpose of using the other area's standardized amount for inpatient operating costs or the wage index value, or both (September 6, 1990 interim final rule with comment period (55 FR 36754), June 4, 1991 final rule with comment period (56 FR 25458), and June 4, 1992 proposed rule (57 FR 23631)). Implementing regulations in subpart L of part 412 (§§ 412.230 *et seq.*) set forth criteria and conditions for redesignations for purposes of the wage index or the average standardized amount, or both, from rural to urban, rural to rural, or from an urban area to another urban area, with special rules for SCHs and rural referral centers.

Effective with reclassifications for FY 2003, section 1886(d)(10)(D)(vi)(II) of the Act provides that the MGCRB must use the average of the 3 years of hourly wage data from the most recently published data for the hospital when evaluating a hospital's request for reclassification. The regulations at § 412.230(e)(2)(ii) stipulate that the wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes. To evaluate applications for wage index reclassifications for FY 2004, the MGCRB used the 3-year average hourly wages published in Table 2 of the August 1, 2002 IPPS final rule (67 FR 50135). These average hourly wages are taken from data used to calculate the wage indexes for FY 2001, FY 2002, and FY 2003, based on cost reporting periods beginning during FY 1997, FY 1998, and FY 1999, respectively.

Last year, we received a comment suggesting that we allow for the correction of inaccurate data from prior years as part of a hospital's bid for geographic reclassification (67 FR 50027). The commenter suggested that not to allow corrections to the data results in inequities in the calculation in the average hourly wage for purposes of reclassification. In the August 1, 2002 IPPS final rule, we responded:

''Hospitals have ample opportunity to verify the accuracy of the wage data used to calculate their wage index and to request revisions, but must do so within the prescribed timelines. We consistently instruct hospitals that they are responsible for reviewing their data and availing themselves to the opportunity to correct their wage data within the prescribed timeframes. Once the data are finalized and the wage indexes published in the final rule, they may not be revised, except through the mid-year correction process set forth in the regulations at § 412.63(x)(2). Accordingly, it has been our consistent policy that if a hospital does not request corrections within the prescribed timeframes for the development of the wage index, the hospital may not later seek to revise its data in an attempt to qualify for MGCRB reclassification.

''Allowing hospitals the opportunity to revise their data beyond the timelines required to finalize the data used to calculate the wage index each year would lessen the importance of complying with those deadlines. The likely result would be that the data used to compute the wage index would not be as carefully scrutinized because

§ 412.23 Excluded hospitals: Classifications.

* * * * *

(e) *Long-term care hospitals.* * * *

(3) *Calculation of average length of stay.* * * *

(ii) If a change in the hospital's Medicare average length of stay is indicated, the calculation is made by the same method for the period of at least 5 months of the immediately preceding 6-month period.

(iii) If a hospital has undergone a change of ownership (as described in § 489.18 of this chapter) at the start of a cost reporting period or at any time within the period of at least 5 months of the preceding 6-month period, the hospital may be excluded from the prospective payment system as a long-term care hospital for a cost reporting period if, for the period of at least 5 months of the 6 months immediately preceding the start of the period (including time before the change of ownership), the hospital has the required Medicare average length of stay, continuously operated as a hospital, and continuously participated as a hospital in Medicare.

* * * * *

§ 412.25 [Amended]

5. In § 412.25(e)(4), introductory text, the reference "paragraph (h)(3) of this section" is revised to read "paragraph (e)(3) of this section".

6. Section 412.87 is amended by revising paragraph (b)(3) to read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(b) *Eligibility criteria.* * * *

(3) The DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount set at 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

7. Section 412.105 is amended by—

A. In paragraph (a)(1), introductory text, revising the phrase "paragraph (f) of this section" to read "paragraphs (f) and (h) of this section".

B. In paragraph (a)(1)(i), revising the phrase "affiliated groups" to read "Medicare GME affiliated groups".

C. Revising paragraph (b).

D. Adding a sentence at the end of paragraph (f)(1)(v).

E. In paragraph (f)(1)(vi), revising the phrase "affiliated group" to read "Medicare GME affiliated group".

F. Revising paragraph (f)(1)(x).

The revisions and additions read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(b) *Determination of number of beds.* For purposes of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period. This count excludes bed days associated with—

(1) Beds in any other units or wards where the level of care provided would not be payable under the acute care hospital inpatient prospective payment system;

(2) Beds in units unoccupied for the previous 3 months;

(3) Beds that could not be made available for inpatient occupancy within 24 hours.

(4) Beds in excluded distinct part hospital units;

(5) Beds otherwise countable under this section used for outpatient observation services (unless the patient is subsequently admitted for acute inpatient care), skilled nursing swing-bed services, or ancillary labor/delivery services;

(6) Beds or bassinets in the healthy newborn nursery; and

(7) Custodial care beds;

* * * * *

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.* (1) * * *

(v) * * * Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, FTE residents in a rural track program are included in the urban hospital's rolling average calculation described in this paragraph (f)(1)(v).

* * * * *

(x) An urban hospital that establishes a new residency program (as defined in § 413.86(g)(13) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.86(g)(12) of this subchapter effective for discharges occurring on or after April 1, 2002 and before October 1, 2003, and the applicable provisions of § 413.86(g)(12) of this subchapter effective for discharges occurring on or after October 1, 2003.

* * * * *

7. Section 412.106 is amended by revising paragraphs (a)(1)(ii) and (b)(4)(i) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) General considerations. (1) * * *

(ii) For purposes of this section, the number of patient days in a hospital includes only those days attributable to units or wards of the hospital providing acute care services generally payable under the prospective payment system and excludes patient days associated with—

(A) Beds in excluded distinct part hospital units;

(B) Beds otherwise countable under this section used for outpatient observation services (unless the patient is subsequently admitted for acute inpatient care), skilled nursing swing-bed services, or ancillary labor/delivery services; and

(C) Beds in any other units or wards where the level of care provided would not be payable under the acute care hospital inpatient prospective payment system.

* * * * *

(b) *Determination of a hospital's disproportionate payment percentage.* * * *

(4) *Second computation.* * * *

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

* * * * *

that there has been some confusion and we have had adverse court decisions, we do not anticipate this clarification would have a significant impact on payments. We do not have data available that would enable us to identify those hospitals that have not been applying this policy and, therefore, would be required to change their policy. Consequently, we are unable to quantify the impacts of this clarification.

5. Labor, Delivery, Recovery, and Postpartum Beds and Days

Similarly, in the case of labor, delivery, recovery, and postpartum rooms, we would clarify that it is necessary to apportion the days and costs of a patient stay between the labor/delivery ancillary cost centers and the routine adults and pediatrics cost center on the basis of the percentage of time during the entire stay associated with these various services. Because this is a clarification of existing policy, we do not anticipate this proposed change would have a significant payment impact. However, we do not have data available that would enable us to identify those hospitals that have not been applying this policy and, therefore, would be required to change their policy. Consequently, we are unable to quantify the impacts of this clarification.

6. Days Associated With Demonstration Projects Under Section 1115 of the Act

Some States have demonstration projects that provide family planning or outpatient drug benefits that are limited benefits that do not include Medicaid coverage for inpatient services. In this proposed rule, we also would clarify that any hospital inpatient days attributed to a patient who is not eligible for Medicaid inpatient hospital benefits either under the approved State plan or through a section 1115 waiver must not be counted in the calculation of Medicaid days for purposes of determining a hospital's DSH percentage.

We estimated the potential impact of the proposed clarification to our policy of excluding days associated with inpatients who are eligible only for Medicaid outpatient benefits. We identified the percentage of individuals receiving only outpatient family planning benefits under Medicaid compared to all Medicaid-eligible beneficiaries (this is currently the only outpatient-only category for which we have numbers of eligible beneficiaries). These percentages were calculated on a statewide basis for each State with a family planning benefit. Based on these percentages, assuming family planning beneficiaries use inpatient services at the same rate as all other Medicaid beneficiaries, we estimated the amount of total Medicare DSH payments for each State that may be attributable to family planning beneficiaries' use of inpatient services.

For example, in Alabama, total Medicare DSH payments in 1999 (the latest year for which a complete database of cost reports from all hospitals is available) were $97.1 million. Because the percentage of family planning beneficiaries to total Medicaid eligible beneficiaries is 11.24 percent, we estimated 11.24 percent of $97.1 million in Medicare DSH payments, or $10.9 million, is the maximum amount of Medicare DSH that may currently be attributable to the inclusion of inpatient days for individuals who are only eligible for outpatient family planning Medicaid benefits. Based on this analysis, we have identified the potential impact upon hospitals to be as much as $290 million in reduced DSH payments from the Medicare program to those hospitals in FY 2004. Of this amount, $170 million is attributable to California. This amount is not an impact on State programs nor does it require States to spend any additional money. We also note that we are not aware of any specific hospitals that are including inpatient days attributable to individuals with no inpatient Medicaid benefits. Therefore, this estimate reflects the maximum potential impact, but the actual impact is very likely to be much less.

We are unable to estimate the effect of this clarification on specific hospitals because we are not aware of specific hospitals that are presently including those inpatient days in their calculation of Medicaid days for purposes of determining their Medicare DSH percentage. However, we expect the impact on any particular hospital would be minimal (with no impact on the level of beneficiary services), because the days attributable to patients receiving these limited benefit programs should be only a small portion of the overall Medicaid days at any particular hospital. No other provider types would be affected.

7. Dual-Eligible Patient Days

We are proposing to change our policy for counting days for patients who are Medicare beneficiaries and also eligible for Medicaid, to begin to count in the Medicaid fraction of the DSH patient percentage the patient days of these dual-eligible Medicare beneficiaries whose Medicare coverage has expired. Our current policy regarding dual-eligible patient days is they are counted in the Medicare fraction and excluded from the Medicaid fraction, even if the patient has no Medicare Part A coverage or coverage has been exhausted. However, we recognize it is often difficult for fiscal intermediaries to differentiate the days for dual-eligible patients whose Part A coverage has been exhausted. We believe the impact of this proposed change would be minimal, both because situations where dual-eligible patients exhaust their Medicare benefits occur infrequently, and because, due to the administrative difficulty separately identifying these days, in many cases they are already included in the hospital's Medicaid fraction. Accordingly, we do not have data available to allow us to quantify the impact of this proposed change precisely.

8. Medicare+Choice (M+C) Days

We have received questions whether patients enrolled in a Medicare+Choice (M+C) Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The questions stem from whether M+C plan enrollees are entitled to Medicare Part A because M+C plans are administered through Medicare Part C. We are proposing to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage. These patient days should be included in the count of total patient days in the Medicaid fraction (the denominator), and the patient's days for an M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction.

We do not have data readily available to assess the impacts of this proposed change. In particular, it appears likely that there is some variation in how these days are currently being handled from one hospital and fiscal intermediary to the next. Nonetheless, we believe there should not be a major impact associated with this proposed change.

B. Costs of Approved Nursing and Allied Health Education Activities

1. Continuing Education

In section IV.E. of the preamble of this proposed rule, we are proposing to clarify further the distinction between continuing education, which is not eligible for pass-through payment, and approved educational programs, which are eligible for pass-through payment. An approved program that qualifies for pass-through payment is generally a program of long duration designed to develop trained practitioners in a nursing or allied health discipline, such as professional nursing, in which the individual learns ''value-added'' skills that enable him or her to work in a particular capacity upon completion of the program. Such a program is in contrast to a continuing education program in which a practitioner, such as a registered nurse, receives training in a specialized skill or a new technology. While such training is undoubtedly valuable in enabling the nurse to treat patients with special needs, the nurse, upon completion of the program, continues to function as a registered nurse, albeit one with an additional skill. We are proposing to clarify our policy concerning not allowing pass-through payment for continuing education because it has come to our attention that certain programs, which in our view constitute continuing education, such as pharmacy or clinical pastoral education, are inappropriately receiving pass-through payment.

To the extent that Medicare would no longer pay for such programs as pharmacy and clinical pastoral education, Medicare payments would be reduced. We believe that these two programs comprise a small fraction of the approximately $230 million that are paid for all nursing and allied health education programs under Medicare.

2. Nonprovider-Operated Nursing and Allied Health Education Programs With Wholly Owned Subsidiary Educational Institutions

As discussed in section IV.E.3. of this proposed rule, we are proposing that Medicare would not recoup reasonable cost payment from hospitals that have received pass-through payment for portions of cost reporting periods occurring on or before October 1, 2003 (the effective date of finalizing this proposed rule) for costs of nursing or allied health education program(s) where the program(s) had originally been operated by the hospital, and then operation

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 412, 413, 418, 460, 480, 482, 483, 485, and 489

[CMS–1428–F]

RIN 0938–AM80

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that was enacted on December 8, 2003. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2004. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

Among the policy changes that we are making are: Changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)–DRGs and relative weights; changes in the wage data, labor-related share of the wage index, and the geographic area designations used to compute the wage index; changes in the qualifying threshold criteria for and the approval of new technologies and medical services for add-on payments; changes to the policies governing postacute care transfers; changes to payments to hospitals for the direct and indirect costs of graduate medical education; changes to the payment adjustment for disproportionate share rural hospitals; changes in requirements and payments to critical access hospitals (CAHs); changes to the disclosure of information requirements for Quality Improvement Organization (QIOs); and changes in the hospital conditions of participation for discharge planning and fire safety requirements for certain health care facilities.

DATES: The provisions of this final rule are effective on October 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Jim Hart, (410) 786–9520, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Standardized Amounts, Hospital Geographic Reclassifications, Postacute Care Transfers, and Disproportionate Share Hospital Issuesp; Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Critical Access Hospitals, and Long-Term Care (LTC)–DRGs Issues;

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Acronyms

ACGME—Accreditation Council on Graduate Medical Education
AHIMA—American Health Information Management Association
AHA—American Hospital Association
AOA—American Osteopathic Association
ASC—Ambulatory Surgical Center
BBA—Balanced Budget Act of 1997, Pub. L. 105–33
BIPA—Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BLS—Bureau of Labor Statistics
CAH—Critical access hospital
CART CMS—Abstraction & Reporting Tool
CBSAs—Core-Based Statistical Areas
CC—Complication or comorbidity
CMS—Centers for Medicare & Medicaid Services
CMSA—Consolidated Metropolitan Statistical Area
COBRA—Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99–272
CoP—Condition of Participation
CPI—Consumer Price Index
CRNA—Certified registered nurse anesthetist
DRG—Diagnosis-related group
DSH—Disproportionate share hospital
ESRD—End-stage renal disease
FDA—Food and Drug Administration
FQHC—Federally qualified health center
FSES—Fire Safety Evaluation System
FTE—Full-time equivalent
FY—Federal fiscal year
GME—Graduate medical education
HCRIS—Hospital Cost Report Information System
HIPC—Health Information Policy Council
HIPAA—Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
HHA—Home health agency
HPSA—Health Professions Shortage Area
ICD–9–CM—International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–PCS—International Classification of Diseases, Tenth Edition, Procedure Coding System
ICF/MRs—Intermediate care facilities for the mentally retarded
IME—Indirect medical education
IPPS—Acute care hospital inpatient prospective payment system
IPF—Inpatient psychiatric facility
IRF—Inpatient rehabilitation facility
JCAHO—Joint Commission on the Accreditation of Healthcare Organizations
LAMA—Left Against Medical Advice
LTC–DRG—Long-term care diagnosis-related group

For these reasons, we have decided not to finalize our proposal stated in the May 19, 2003 proposed rule to include dual-eligible beneficiaries who have exhausted their Part A hospital coverage in the Medicaid fraction. Instead, we are adopting a policy to include the days associated with dual-eligible beneficiaries in the Medicare fraction, whether or not the beneficiary has exhausted Medicare Part A hospital coverage. If the patient is entitled to Medicare Part A and SSI, the patient days will be included in both the numerator and denominator of the Medicare fraction. This policy will be effective for discharges occurring on or after October 1, 2004. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with dual-eligible beneficiaries in the Medicare fraction of the DSH calculation.

4. Medicare+Choice (M+C) Days

Under existing § 422.1, an M+C plan means ''health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.'' Generally, each M+C plan must provide coverage of all services that are covered by Medicare Part A and Part B (or just Part B if the M+C plan enrollee is only entitled to Part B).

We have received questions whether the patient days associated with patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The question stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C.

We note that, under existing regulations at § 422.50, an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A. In the proposed rule of May 19, 2003 (68 FR 27208), we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DSH patient percentage. Under our proposal, these patient days would be included in the Medicaid fraction. The patient days of dual-eligible M+C beneficiaries (that is, those also eligible for Medicaid) would be included in the count of total patient days in both the numerator and denominator of the Medicaid fraction.

Comment: Several commenters indicated that they appreciated CMS's attention to this issue in the proposed rule. The commenters also indicated that there has been insufficient guidance on how to handle these days in the DSH calculation. However, several commenters disagreed with excluding these days from the Medicare fraction and pointed out that these patients are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program.

Response: Although there are differences between the status of these beneficiaries and those in the traditional fee-for-service program, we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A. We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction. As noted previously, if the beneficiary is also an SSI recipient, the patient days will be included in the numerator of the Medicare fraction. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation.

M. Payment Adjustments for Low-Volume Hospitals (§ 412.101)

Section 406 of Public Law 108–173 amended section 1886(d) of the Act to add a new subclause (12) to provide for a new payment adjustment to account for the higher costs per discharge of low-volume hospitals under the IPPS. Section 1886(d)(12)(C)(i) of the Act, as added by section 406, defines a low-volume hospital as a ''subsection (d) hospital * * * that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year.'' Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' refers to total discharges, and not merely to Medicare discharges. Specifically, the term refers to the ''inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.'' Finally, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between ''the standardized cost-per-case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.'' The statute thus mandates the Secretary to develop an empirically justifiable adjustment formula based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

MedPAC has published an analysis of the financial performance and cost profiles of low-volume hospitals (MedPAC June 2001 Report to Congress, page 66). Its analysis indicated that hospitals with 500 discharges or less generally have negative Medicare margins. Specifically, hospitals with 200 discharges or less have margins of −16.4 percent, and hospitals with 201 to 500 discharges have margins of −2.1 percent. MedPAC's analysis further revealed that hospitals with a small volume of discharges have higher costs per discharge than larger facilities, after controlling for the other cost factors recognized in the payment system. MedPAC's analysis thus indicates that low-volume providers are disadvantaged by payment rates based on average volume. In analyzing the relationship between costs per case and discharges, MedPAC also found that this relationship begins to level off and reaches zero variation at around 500 discharges. Therefore, MedPAC recommended an adjustment formula in the form of:

1.25 −(.0005*D), if D<500 discharges

Where 1.25 represents the maximum 25-percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and ''D'' is the number of discharges.

Using FY 2001 cost report data, we found an even larger disparity than MedPAC found between low-volume providers and their higher-volume counterparts. Although Medicare margins remain healthy overall at 9.32 percent, the Medicare margin for providers with 200 or less discharges is −46.26 percent, and the margin for providers with 201 to 500 discharges is −11.74 percent. For the May 18, 2004 proposed rule, we employed a bivariate regression analysis to determine the fit between total hospital discharges and operating costs from FY 2001.

As discussed in the proposed rule, we found a very strong correlation between costs and the total number of discharges. We then examined the variation in cost-per-case among subsection (d) hospitals, using both log

reporting periods beginning on or after July 1, 1991.

(1) * * *

(iv) (A) * * *

(B) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital's otherwise applicable FTE resident cap may be reduced if its reference resident level is less than its otherwise applicable FTE resident cap in a reference cost reporting period, in accordance with the provisions of § 413.79(c)(3) of this subchapter. The reduction is 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level.

(C) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap (up to 25 additional FTEs) if the criteria specified in § 413.79(c)(4) of this subchapter are met.

* * * * *

■ 15. Section 412.106 is amended by—

■ A. Revising paragraphs (a)(1)(ii)(B) and (a)(1)(ii)(C).

■ B. Adding a new paragraph (a)(1)(ii)(D).

■ C. Revising paragraph (b)(2)(i) introductory text.

■ D. In paragraph (a)(1)(iii), removing the cross-reference ''§ 412.62(f)'' and adding in its place ''§ 412.62(f) or § 412.64''.

■ E. Revising paragraphs (d)(2)(ii), (d)(2)(iii), and (d)(2)(iv) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) General considerations.

(1) * * *

(ii) * * *

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or ancillary labor/delivery services. This exclusion would not apply if a patient treated in an observation bed is ultimately admitted for acute inpatient care, in which case the beds and days would be included in those counts;

(C) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month); and

(D) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days.

* * * * *

(b) * * *

(2) * * *

(i) Determines the number of patient days that—

* * * * *

(d) *Payment adjustment factor.*

* * * * *

(2) *Payment adjustment factors.*

* * * * *

(ii) If the hospital meets the criteria of paragraph (c)(1)(ii) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital is classified as a rural referral center—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001, and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is greater than or equal to 30 percent, the applicable payment adjustment factor is 5.25 percent plus 60 percent of the difference between 30 percent and the hospital's disproportionate patient percentage.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital is classified as a sole community hospital—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 10 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is equal to or greater than 30 percent, the applicable payment adjustment factor is 10 percent.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*iii*) The maximum payment adjustment factor is 12 percent.

(C) If the hospital is classified as both a rural referral center and a sole community hospital, the payment adjustment is—

(*1*) For discharges occurring before April 1, 2001, the greater of—

(*i*) 10 percent; or

(*ii*) 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the greater of the adjustments determined under paragraphs (d)(2)(ii)(A) or (d)(2)(ii)(B) of this section.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus

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Appendix A—Regulatory Analysis of Impacts

I. Background and Summary

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this final rule is a major rule as defined in 5 U.S.C. 804(2). Based on the overall percentage change in payments per case estimated using our payment simulation model (a 5.8 percent increase), we estimate that the total impact of these proposed changes for FY 2005 payments compared to FY 2004 payments to be approximately a $5.05 billion increase. This amount does not reflect changes in hospital admissions or case-mix intensity, which would also affect overall payment changes.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million to $25 million in any 1 year. For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we previously defined a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA). However, under the new labor market definitions that we are proposing to adopt, we no longer employ NECMAs to define urban areas in New England. Therefore, we now define a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent NECMA. Thus, for purposes of the IPPS, we continue to classify these hospitals as urban hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any proposed rule (or a final rule that has been preceded by a proposed rule) that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This final rule will not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule in light of Executive Order 13132 and have determined that it would not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

The following analysis, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act. The final rule will affect payments to a substantial number of small rural hospitals as well as other classes of hospitals, and the effects on some hospitals may be significant.

II. Objectives

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs. In addition, we share national goals of preserving the Medicare Trust Fund.

We believe the changes in this final rule will further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these final changes will ensure that the outcomes of this payment system are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

III. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our final policy changes, as well as statutory changes effective for FY 2005, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but we do not attempt to predict behavioral responses to our policy changes, and we do not make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix. As we have done for previous proposed rules, we solicited comments and information about the anticipated effects of these changes on hospitals and our methodology for estimating them. Any comments that we received in response to the proposed rule are addressed in this final rule.

IV. Hospitals Included In and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs encompass nearly all general short-term, acute care hospitals that participate in the Medicare program. There were 41 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment method for these hospitals. Among other short-term, acute care hospitals, only the 47 such hospitals in Maryland remain excluded from the IPPS under the waiver at section 1814(b)(3) of the Act.

As of July 2004, there are 3,897 IPPS hospitals to be included in our analysis. This represents about 80 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There are also approximately 934 critical access hospitals (CAHs). These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. There are also 1,167 specialty hospitals and units that are excluded from the IPPS. These specialty hospitals include psychiatric hospitals and units, rehabilitation hospitals and units, long-term care hospitals, children's hospitals, and cancer hospitals. The impacts of our policy changes on these hospitals are discussed below.

V. Impact on Excluded Hospitals and Hospital Units

As of July 2004, there were 1,167 specialty hospitals excluded from the IPPS. Of these 1,167 specialty hospitals, 475 psychiatric hospitals, 80 childrens, 11 cancer hospitals and the less than 10 percent of LTCHs that are paid under the LTCH PPS blend methodology are being paid, in whole or in part, on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. The remaining providers—216 rehabilitation and approximately 90 percent of the 338 long-term care hospitals are paid 100 percent of the Federal rate under the IRF and LTCH PPS, respectively. In addition, there were 1,374 psychiatric units (paid on a reasonable cost basis) and 1,001 rehabilitation units (paid under IRF PPS) in hospitals otherwise subject to the IPPS. Under § 413.40(a)(2)(i)(A), the rate-of-increase ceiling is not applicable to the 47 specialty hospitals and units in Maryland that are paid in accordance with the waiver at section 1814(b)(3) of the Act.

In the past, hospitals and units excluded from the IPPS have been paid based on their reasonable costs subject to limits as established by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Hospitals that continue to be paid based on their reasonable costs are subject to TEFRA limits for FY 2005. For these hospitals, the update is the percentage increase in the excluded hospital market basket, currently estimated at 3.3 percent.

Inpatient rehabilitation facilities (IRFs) are paid under a prospective payment system

precisely to the average hourly wage threshold for rural referral centers. Only a limited number of rural referral centers are actually located in urban areas. Effective October 1, 2000, if a hospital located in what is now an urban area was ever a rural referral center, it is reinstated to rural referral center status (65 FR 47089). We are unable to determine how many of these rural referral centers that would not otherwise have qualified for reclassification would now be able to meet the 82 percent threshold. However, this change does not affect the aggregate level of Medicare expenditures since reclassification decisions are budget neutral under section 1886(d)(8)(B) of the Act. The exercise of the Secretary's exception authority to assign a new wage index to certain rural referral centers that failed to be approved for reclassification in FY 2005 is not budget neutral. Only one hospital has demonstrated that it meets the conditions for receiving this special exception. The aggregate impact on program payments will be in the range of $10 million to $15 million for the 3-years during which this exception will be in effect.

Further, our use of the authority in section 1886(d)(5)(I)(i) of the Act, to provide special protection to a small number of hospitals in States with fewer than 10 people per square mile (as determined using 2000 census data) will only increase Medicare program expenditures by approximately $3 million to $6 million. A total of 9 hospitals have satisfied the criteria for receiving this exception. However, these hospitals are relatively small, and some of them are paid under their hospital specific rates, which restricts the gain from reclassification in most cases to capital PPS payments and payments for outpatient services.

I. Impact of Policy Changes for Available Beds and Patient Days Used in the IME and DSH Adjustments

Under the IPPS, the IME and the DSH adjustments utilize statistics regarding the number of beds and patient days of a hospital to determine the level of the respective payment adjustment. For IME, hospitals receiving this adjustment want to minimize their number of beds in order to maximize their resident-to-bed ratio. For DSH, urban hospitals with 100 or more beds qualify for a higher payment adjustment, so some hospitals have an incentive to maximize their bed count to qualify for higher payments. Existing regulations specify that the number of beds is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period.

In this final rule, we finalized our policy regarding unoccupied beds, observation beds of patients ultimately admitted as inpatients, dual-eligible patient days, and Medicare+Choice patient days. We do not anticipate that these policy changes will have a significant impact on payments. Based on an analysis from our actuarial staff, we anticipate the impact of all four of these policy changes to be less than $50 million for FY 2005.

J. Impact of Proposed Policy on Payment for Direct Costs of Graduate Medical Education

1. Redistribution of Unused Resident Slots

As discussed in section IV.O.2.b. of this preamble, section 422 of Public Law 108–173 added a new section 1886(h)(7) to the Act that provides for reductions in the statutory FTE resident caps under Medicare for certain hospitals and authorizes a ''redistribution'' of the FTE resident slots resulting from the reduction in the FTE resident caps to other hospitals.

For purposes of this final rule, we have estimated the impact of section 422 on hospitals for FY 2005, making assumptions about update factors, geographic (locality) adjustment factors, and the number of unused residency positions for each hospital. For purposes of calculating the impact for direct GME payments, we used the projected national average per resident amount (PRA) for FY 2005 of $82,249, as determined in accordance with existing § 413.86(e)(4)(ii)(B) (redesignated as § 413.77(d)(2)(ii) in this final rule), since section 1886(h)(7)(B)(v) of the Act requires that a hospital that receives an increase in its direct GME FTE resident cap under section 1886(h)(7)(B) of the Act will receive direct GME payments with respect to those additional FTE residents using the locality-adjusted national average PRA. Based on our analysis of hospitals' FTE resident caps and FTE resident counts from the Hospital Cost Report Information System (HCRIS) for the most recent cost reporting periods ending on or before September 30, 2002, and making assumptions for hospitals that submit a timely request to use their cost report that includes July 1, 2003, we estimate that approximately 2,600 FTE resident slots that were previously unfilled (and therefore, no direct GME or IME payments were made for those slots) will be redistributed to and filled by hospitals that request an increase to their FTE residents caps under section 1886(h)(7)(B) of the Act. (We note that this estimate of 2,600 slots is not necessarily the same as the estimate we will ultimately use to redistribute resident positions under section 1886(h)(7)(B)) of the Act. Since payments for direct GME are determined based on a hospital's Medicare inpatient utilization, for purposes of this impact, we have applied a factor of .35 as the average Medicare inpatient utilization. Accordingly, for FY 2005, we estimate an increase of $75.6 million in direct GME payments.

For purposes of estimating the impact on IME payments, we used an IME formula multiplier of 0.66, since section 1886(d)(5)(B)(ix) of the Act states that for a hospital whose FTE resident cap is increased as a result of a redistribution of unused resident positions, the IME adjustment factor is to be calculated using a formula multiplier of 0.66 with respect to any additional residents counted by the hospital as a result of that increase in the hospital's FTE resident cap. Based on an estimate of unused resident positions using FTE resident data from HCRIS for the most recent cost reporting periods ending on or before September 30, 2002, and making assumptions for hospitals that submit a timely request to use their cost report that includes July 1, 2003, we estimate that for FY 2005, IME payments will increase by approximately $66.5 million. Thus, since section 422 is not effective until the fourth quarter of FY 2005 (that is, July 1, 2005), the estimated total increase in Medicare payments for FY 2005 attributable to section 422 is $35.53 million ([$75.6 million + $66.5 million] divided by 4).

2. Per Resident Amount: Extension of Update Limitation on High-Cost Programs

In section IV.O.4. of the preamble of this final rule, we discuss our implementation of section 711 of Public Law 108–173, which freezes the annual CPI–U inflation factors to hospital-specific PRAs for direct GME payments for those PRAs that exceed the established ceiling for FYs 2004 through 2013. Under existing regulations, for FY 2005, if a hospital's PRA for the previous cost reporting period would be greater than 140 percent of the locality-adjusted national average PRA for that same previous cost reporting period, the hospital's PRA would be updated for inflation, except that the CPI–U applied for a 12-month period is reduced by 2 percentage points. Under the new provisions of section 711 of Public Law 108–173 for FY 2005, if a hospital-specific PRA for the previous cost period would be greater than 140 percent of the locality-adjusted national average PRA for that same previous cost reporting period, the hospital-specific PRA would be frozen at the FY 2004 PRA, and not updated for inflation. Therefore, the impact in direct GME payments for FY 2005 (attributable to section 711 of the Public Law 108–173) is the difference between updating the PRAs by the applicable CPI–U inflation factor minus 2 percentage points, and not updating the PRAs by any CPI–U inflation factor. We have calculated an impact for this provision, but the resulting savings are negligible (less than $100,000).

3. Residents Training in Nonhospital Settings

In section IV.O.5. of the preamble of this final rule, we discuss our implementation of section 713 of Public Law 108–173, which, through a moratorium, allows hospitals to count allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME without regard to the financial arrangements between the hospital and the teaching physician practicing in the nonhospital setting in which the resident is assigned. We are unable to quantify the impact of these provisions because we do not know the number of residents or programs that are affected by these changes.

In addition, under section IV.O.5 of this preamble, we discuss our changes related to requirements for written agreements for residency training in nonhospital settings. We revised the regulations to allow hospitals to count residents training in a nonhospital setting if the hospital meets at least one of the following criteria: (1) There is a written agreement between the hospital and the nonhospital site stating that the hospital will incur all or substantially all of the costs of training in the nonhospital setting. If the hospital chooses the written agreement option, the existing requirements as specified in the regulations at 413.100(c)(2)(i) and 413.78(d) (redesignated 413.86(f)(4)) would apply. (2) The hospital is paying those costs

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 413, and 489

[CMS–1533–FC]

RIN 0938–AO70

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems, and to implement certain provisions made by the Deficit Reduction Act of 2005 (Pub. L. 109–171), the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief and Health Care Act of 2006 (Pub. L. 109–432), and the Pandemic and All Hazards Preparedness Act (Pub. L. 109–417). In addition, in the Addendum to this final rule with comment period, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. We also are setting forth the rate of increase limits for certain hospitals and hospital units excluded from the IPPS that are paid on a reasonable cost basis subject to these limits, or that have a portion of a prospective payment system payment based on reasonable cost principles. These changes are applicable to discharges occurring on or after October 1, 2007.

In this final rule with comment period, as part of our efforts to further refine the diagnosis related group (DRG) system under the IPPS to better recognize severity of illness among patients, for FY 2008, we are adopting a Medicare Severity DRG (MS DRG) classification system for the IPPS. We are also adopting the structure of the MS–DRG system for the LTCH prospective payment system (referred to as MS–LTC–DRGs) for FY 2008.

Among the other policy decisions and changes that we are making, we are making changes related to: limited revisions of the reclassification of cases to MS–DRGs, the relative weights for the MS–LTC–DRGs; applications for new technologies and medical services add-on payments; the wage data, including the occupational mix data, used to compute the FY 2008 wage indices; payments to hospitals for the indirect costs of graduate medical education; submission of hospital quality data; provisions governing the application of sanctions relating to the Emergency Medical Treatment and Labor Act of 1986 (EMTALA); provisions governing the disclosure of physician ownership in hospitals and patient safety measures; and provisions relating to services furnished to beneficiaries in custody of penal authorities.

DATES: *Effective Date:* This final rule with comment period is effective October 1, 2007 and applies to discharges occurring on or after that date.

Comment Date: We will consider public comments only on the provisions of section V., Changes to the IPPS for Capital Related Costs, of the preamble of this final rule with comment period, if we receive them at one of the addresses provided below, no later than 5 p.m. on November 20, 2007.

ADDRESSES: In commenting on the provisions of section V. of the preamble of this final rule with comment period, please refer to file code CMS–1533–FC.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Submit electronic comments on CMS regulations with an open comment period". (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1533–FC, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1533–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriately for hand or courier delivery may be delayed and received after the comment period.

Submitting Comments: You can assist us by referencing the file code CMS–1533–FC and the specific "issue identifier" that precedes section V., Changes to the IPPS for Capital Related Costs.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

FOR FURTHER INFORMATION CONTACT: Marc Hartstein, (410) 786–4548, Operating Prospective Payment, Diagnosis Related Groups (DRGs), Wage Index, New Medical Services and Technology Add-On Payments, and Hospital Geographic Reclassifications Issues.

2. Technical Correction: Inclusion of Medicare Advantage Days in the Medicare Fraction of the Medicare DSH Calculation

In the FY 2005 IPPS final rule (69 FR 49099), we discussed in the preamble our policy change to reflect the inclusion of the days associated with Medicare + Choice (now Medicare Advantage) beneficiaries under Medicare Part C in the Medicare fraction of the DSH calculation. In that rule, we indicated that we were revising the regulation text at § 412.106(b)(2)(i) to incorporate this policy. However, we inadvertently did not make a change in the regulation text to conform to the preamble language. We also inadvertently did not propose to change § 412.106(b)(2)(iii) in the FY 2005 final rule, although we intended to do so. Section 412.106(b)(2)(i) of the regulations discusses the numerator of the Medicare fraction of the Medicare disproportionate patient percentage (DPP) calculation while § 412.106(b)(2)(iii) of the regulations discusses the denominator of the Medicare fraction of the Medicare DPP. We intended to amend the regulation text with respect to both the numerator and the denominator of the Medicare fraction of the Medicare DPP. Therefore, in this final rule with comment period, we are making this technical correction to § 412.106(b)(2)(i) and to § 412.106(b)(2)(iii) to make them consistent with the preamble language of the FY 2005 IPPS final rule and to effectuate the policy iterated in that rule.

With respect to the technical correction that we are making to § 412.106(b)(2)(iii), we note that we ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for a period for public comment before a provision such as this would take effect. However, we can waive this procedure if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the notice issued. We find it unnecessary to undertake notice and comment rulemaking in this instance for the additional change to § 412.106(b)(2)(iii) because this notice merely provides technical corrections to the regulations and does not make any substantive changes to the regulations or our existing policy. Therefore, under 5 U.S.C. 533(b)(B), for good cause, we waive notice and comment procedures.

F. Hospital Emergency Services Under EMTALA (§ 489.24)

1. Background

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on certain Medicare-participating hospitals and CAHs. (Throughout this section of this final rule with comment period, when we reference the obligation of a "hospital" under these sections of the Act and in our regulations, we mean to include CAHs as well.) These obligations concern individuals who come to a hospital emergency department and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether they are beneficiaries of any program under the Act.

The statutory provisions cited above are frequently referred to as the Emergency Medical Treatment and Labor Act (EMTALA), also known as the patient antidumping statute. EMTALA was passed in 1986 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99–272. Congress incorporated these antidumping provisions within the Social Security Act to ensure that individuals with emergency medical conditions are not denied essential lifesaving services because of a perceived inability to pay.

Under section 1866(a)(1)(I)(i) of the Act, a hospital that fails to fulfill its EMTALA obligations under these provisions may be liable for termination of its Medicare provider agreement, which would result in loss of all Medicare and Medicaid payments.

Section 1867 of the Act sets forth requirements for medical screening examinations for individuals who come to the hospital and request examination or treatment for a medical condition. The section further provides that if a hospital finds that such an individual has an emergency condition, it is obligated to provide that individual with either necessary stabilizing treatment or an appropriate transfer to another medical facility where stabilization can occur.

The EMTALA statute also outlines the obligation of hospitals to receive appropriate transfers from other hospitals. Section 1867(g) of the Act states that a participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires these specialized capabilities or facilities if the hospital has the capacity to treat the individual.

The regulations implementing section 1867 of the Act are found at 42 CFR 489.24.

2. Recent Legislation Affecting EMTALA Implementation

a. Secretary's Authority To Waive Requirements During National Emergencies

Section 1135 of the Act authorizes the Secretary to temporarily waive or modify the application of several requirements of titles XVIII, XIX, or XXI of the Act (the Medicare, Medicaid, and State Children's Health Insurance Program provisions), and their implementing regulations in an emergency area during an emergency period. Section 1135(g)(1) of the Act defines an "emergency area" as the geographical area in which there exists an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act (subsection A) and a public health emergency declared by the Secretary pursuant to section 247d of Title 42 of the United States Code. Section 1135(g)(1) of the Act also defines an "emergency period" as the period during which such a disaster exists. Section 1135(b) of the Act lists the actions for which the otherwise applicable statutory provisions and implementing regulations may be waived. Included among these actions are, in subparagraph (b)(3)(A), a transfer of an individual who has not been stabilized in violation of the EMTALA requirements restricting transfer until an individual has been stabilized (section 1867(c) of the Act) and, in subparagraph (b)(3)(B), the direction or relocation of an individual to receive medical screening in an alternate location, in accordance with an appropriate State emergency preparedness plan.

Section 1135(b) of the Act further states that a waiver or modification provided for under section 1135(b)(3) of the Act shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. All other waivers arising out of section 1135(b) of the Act (except for section 1135(b)(7)) ordinarily may continue in effect for the duration of the declaration of emergency or disaster, or the declaration of a public health emergency, or for 60-day periods as described in section 1135(e)(1) of the Act.

To take into account the effect of section 1135(b)(3)(A) waivers on the EMTALA requirements, § 489.24(a)(2) of our regulations specifies that sanctions

classification of discharges that do not reflect real changes in case mix, CMS may adjust the standardized amount for subsequent fiscal years so as to eliminate the effect of such coding and classification changes.

* * * * *

(i) * * *

(2) *Amount of adjustment.* A hospital located in a county that meets the criteria under paragraphs (i)(1)(i) through (i)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the postreclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the postreclassified wage index of the MSA or rural statewide area in which the qualifying county is located, weighted by the overall percentage of the hospital employees residing in the qualifying county who are employed in any MSA with a higher wage index.

* * * * *

■ 7. The heading of Subpart F is revised to read as follows:

Subpart F—Payments for Outlier Cases, Special Treatment Payment for New Technology, and Payment Adjustment for Certain Replaced Devices

■ 8. Section 412.88 is amended by revising the introductory text of paragraph (a)(2) to read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) * * *

(2) If the costs of the discharge (determined by applying the operating cost to charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

* * * * *

■ 9. A new undesignated center heading and a new § 412.89 are added under Subpart F following § 412.88 to read as follows:

Payment Adjustment for Certain Replaced Devices

§ 412.89 Payment adjustment for certain replaced devices.

(a) *General rule.* For discharges occurring on or after October 1, 2007, the amount of payment for a discharge described in paragraph (b) of this section is reduced when—

(1) A device is replaced without cost to the hospital;

(2) The provider received full credit for the cost of a device; or

(3) The provider receives a credit equal to 50 percent or more of the cost of the device.

(b) *Discharges subject to payment adjustment.* (1) Payment is reduced in accordance with paragraph (a) of this section only if the implantation of the device determines the DRG assignment.

(2) CMS lists the DRGs that qualify under paragraph (b)(1) of this section in the annual final rule for the hospital inpatient prospective payment system.

(c) *Amount of reduction.* (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DRG payment.

(2) For a device for which the hospital received a full or partial credit, the amount credited is subtracted from the DRG payment.

■ 10. Section 412.96 is amended by adding a new paragraph (g)(4), to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(g) * * *

(4) A hospital that submits a written request on or after October 1, 2007, to cancel its reclassification under § 412.103(g) is deemed to have cancelled its status as a rural referral center effective on the same date the cancellation under § 412.103(g) takes effect. The provision of this paragraph (g)(4) applies to hospitals that qualify as rural referral centers under § 412.96 based on rural status acquired under § 412.103.

* * * * *

■ 11. Section 412.103 is amended by revising paragraph (g) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassifications as rural.

* * * * *

(g) *Cancellation of classification*—(1) *Hospitals other than rural referral centers.* Except as provided in paragraph (g)(2) of this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of its current cost reporting period.

(ii) The hospital's cancellation of the classification is effective beginning with the next full cost reporting period.

(2) *Hospitals classified as rural referral centers.* For a hospital that was classified as a rural referral center under § 412.96 based on rural reclassification under this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year and after being paid as rural for at least one 12-month cost reporting period.

(ii) The hospital's cancellation of the classification is not effective until it has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following such 12-month cost reporting period.

(iii) The provisions of paragraphs (g)(2)(i) and (g)(2)(ii) of this section are effective for all written requests submitted by hospitals on or after October 1, 2007, to cancel rural reclassifications.

■ 12. Section 412.106 is amended by—

■ a. Revising paragraph (b)(2)(i).

■ b. Revising paragraph (b)(2)(iii).

The revisions read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) * * *

(2) * * *

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (or Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

* * * * *

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (or Medicare Advantage (Part C)).

* * * * *

■ 13. Section 412.230 is amended by adding a new paragraph (d)(2)(v) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(1) * * *

(2) * * *

(v) For applications submitted for reclassification effective in FY 2009 and thereafter, a campus of a multicampus hospital that is located in a geographic area different from the area associated with the provider number of the entire multicampus hospital may seek reclassification to another CBSA using the composite wage data of the entire multicampus hospital as its hospital-specific data.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, and 476

[CMS–1518–F; CMS–1430–F]

RIN 0938–AQ24; RIN 0938–AQ92

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems and to implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. We also are setting forth the update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits.

We are updating the payment policy and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes made by the Affordable Care Act. In addition, we are finalizing an interim final rule with comment period that implements section 203 of the Medicare and Medicaid Extenders Act of 2010 relating to the treatment of teaching hospitals that are members of the same Medicare graduate medical education affiliated groups for the purpose of determining possible full-time equivalent (FTE) resident cap reductions.

DATES: *Effective dates:* These final rules are effective on October 1, 2011, except for the provisions of § 412.230(d)(5), which are effective September 1, 2011. Effective July 29, 2011, the interim rule published March 14, 2011, at 76 FR 13515, is confirmed as final without change.

Applicability dates: The update to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits is applicable beginning on or after October 1, 2011. The payment policy and the annual payment rates for inpatient hospital services provided by IPPS hospitals and by long-term care hospitals (LTCHs) and for implementing certain statutory changes made by the Affordable Care Act and other legislation are applicable to discharges occurring on or after October 1, 2011 unless otherwise specified in this final rule.

FOR FURTHER INFORMATION CONTACT:

Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH), and Postacute Care Transfer Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Bridget Dickensheets, (410) 786–8670, Rebasing and Revising of the Market Basket for LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Inpatient Quality Reporting—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Elizabeth Goldstein, (410) 786–6665, Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web, (the Superintendent of Documents' home Web page address is *http://www.gpoaccess.gov/*), by using local WAIS client software, or by telnet to *swais.access.gpo.gov,* then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to this final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables will no longer be published as part of the annual IPPS and LTCH PPS proposed and final rules. Instead, these tables will be available only through the Internet. The IPPS tables for this final rule are available only through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/01_overview.asp.* Click on the link on the left side of the screen titled, ''FY 2012 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2012 final rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/LongTermCareHospitalPPS/LTCHPPSRN/list.asp* under the list item for Regulation Number CMS–1518–F. For complete details on the availability of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Nisha Bhat at (410) 786–4487.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
ALOS Average length of stay
ALTHA Acute Long Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association

adjustment. Prior to the enactment of Public Law 108–173, the formula multiplier was fixed at 1.35 for discharges occurring during FY 2003 and thereafter. In the FY 2005 IPPS final rule, we announced the schedule of formula multipliers to be used in the calculation of the IME adjustment and incorporated the schedule in our regulations at § 412.105(d)(3)(viii) through (d)(3)(xii). Section 502(a) modified the formula multiplier beginning midway through FY 2004 and provided for a new schedule of formula multipliers for FYs 2005 and thereafter as follows:

- For discharges occurring on or after April 1, 2004, and before October 1, 2004, the formula multiplier is 1.47.
- For discharges occurring during FY 2005, the formula multiplier is 1.42.
- For discharges occurring during FY 2006, the formula multiplier is 1.37.
- For discharges occurring during FY 2007, the formula multiplier is 1.32.
- For discharges occurring during FY 2008 and fiscal years thereafter, the formula multiplier is 1.35.

Accordingly, for discharges occurring during FY 2012, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2012 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

Comment: Several commenters supported CMS' proposal to maintain the IME formula multiplier at 1.35. Commenters stated they support the continued IME adjustment factor because IME payments are an important part of guaranteeing both a strong cardiothoracic surgery and general surgery workforce, both of which are currently facing increasing shortages. Another commenter stated that it supported maintaining the current level of IME payments because it is an important funding source for safety net teaching hospitals.

Response: We appreciate the commenters' support. We note that the IME formula multiplier is set by Congress; any change to the multiplier would require a legislative change. Therefore, we are finalizing our proposal that the IME formula multiplier for FY 2012 be set at 1.35, which we estimate will result in an increase in IPPS payments of 5.5 percent for every approximately 10-percent increase in the hospital's resident-to-bed ratio.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) and Indirect Medical Education (IME) (§§ 412.105 and 412.106)

1. Background

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.''

The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan) and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A (including patients who are enrolled in a Medicare Advantage (Part C) plan). The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

As we did in the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25942), we are combining, under section IV.G.2. of this preamble, our discussion of changes to the policies for counting beds in relation to the calculations for the IME adjustment at § 412.105(b) and the DSH payment adjustment at § 412.106(a)(1)(i) and for counting patient days for purposes of the DSH payment adjustment at § 412.106(a)(1)(ii).

2. Policy Change Relating to the Exclusion of Hospice Beds and Patient Days From the Calculation of the Medicare DSH Payment Adjustment and the IME Payment Adjustment

a. Background

As discussed in the FY 2004 IPPS final rule (68 FR 45415 through 45420), when determining a hospital's Medicare DSH payment, our policy is to include patient days in hospital units or wards that would be directly included in determining the allowable costs of inpatient hospital care payable under the IPPS on the Medicare cost report. Under this policy, CMS uses the level of care generally provided in such a unit or ward as a proxy for determining the level of care provided to a particular patient on a particular day within that unit. As stated in the FY 2004 IPPS final rule, our policy is ''not intended to focus on the level or type of care provided to individual patients in a unit, but rather on the level and type of care provided in the unit as a whole.'' (68 FR 45417) In the FY 2005 IPPS final rule, we amended this policy to specifically exclude observation and swing days from the patient day count. In the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25942 and 25943), we proposed to establish an additional exclusion with respect to counting bed days and patient days for patients receiving hospice services in an inpatient setting of a hospital.

b. Hospice Inpatient Services

Section 1861(dd)(1) of the Act defines hospice care to include a limited set of ''items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician

and by the medical director.'' Among those items and services specified under section 1861(dd)(1)(G) of the Act is ''short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days.'' Based on these statutory definitions of hospice care, the Secretary, through regulation at § 418.302, has grouped hospice care services into four categories for payment purposes. Two of these payment categories describe hospice services in an inpatient setting: Inpatient respite care day and general inpatient care day.

Section 418.302(b)(3) of the regulations defines an inpatient respite care day as ''a day on which the individual who has elected hospice care receives care in an approved facility on a short-term basis for respite.'' Section 40.2.2 of Chapter 9 of the Medicare Benefit Policy Manual (*https://www.cms.gov/manuals/Downloads/bp102c09.pdf*) further describes an inpatient respite care day as a short-term inpatient day provided only when necessary to relieve family members or other caregivers caring for the individual at home. Under the Act, inpatient respite care is limited to 5 consecutive days for a given stay. Similarly, the regulations at § 418.302(b)(4) describe a general inpatient care day as ''a day on which an individual who has elected hospice care receives general inpatient care in an inpatient facility for pain control or acute or chronic symptom management which cannot be managed in other settings.''

Section 40.1.5 of Chapter 9 of the Medicare Benefit Policy Manual provides that general inpatient care is appropriate when care for pain control or acute or chronic symptom management cannot feasibly be provided in another setting. This section of the Medicare Benefit Policy Manual further states that such care is ''not equivalent to a hospital level of care.'' That hospice care is not hospital level care is further supported by the provision at § 418.202(e), which provides that general inpatient care and inpatient respite care hospice services can be ''provided in a participating hospice inpatient unit, or a participating hospital or [skilled nursing facility], that additionally meets the standards in § 418.202(a) and (e) regarding staffing and patient areas * * * [and] must conform to the [hospice provider's] written plan of care.''

Furthermore, hospice services provided in an inpatient hospital setting are not payable under the IPPS. Rather, at this time, these services are payable under two of the four prospectively determined all-inclusive categories of care under the hospice payment system. In the FY 2004 IPPS final rule (68 FR 45418), we stated that we believed it ''reasonable to interpret the phrase 'hospital's patient days,' to mean only the hospital's inpatient days at a level of care that would be covered under the IPPS as a means to determine an IPPS payment adjustment.'' In that rule, we acknowledged that it would be ''administratively inefficient and impracticable'' to calculate a hospital' inpatient days based on a determination of whether a particular patient in a particular inpatient bed for a particular stay is receiving a level of care that would be covered under the IPPS (68 FR 45418). Accordingly, we adopted a policy under which we use the level of care that is generally provided in particular units or wards as a proxy for determining whether the care provided to a particular patient is of a type that would be covered under the IPPS. However, we have recognized exceptions to this policy for certain categories of nonacute care, even if that care is provided in an acute care unit.

Therefore, in the FY 2012 IPPS/LTCH PPS proposed rule, we proposed to revise § 412.106(a)(1)(ii) to exclude patient days associated with hospice patients receiving inpatient hospice services in an inpatient hospital setting from the Medicare and Medicaid fractions of the DPP. We also proposed to amend our cost reporting instructions accordingly. Our proposal to exclude hospice inpatient days was analogous to our decision in the FY 2005 IPPS final rule to exclude observation and swing-bed days from the Medicare and Medicaid fractions of the DPP. In that rule, we stated that our policies to exclude observation days and swing-bed days from the count of patient days ''stem from the fact that although the services are provided in beds that would otherwise be available to provide an IPPS level of services, these days are not payable under the IPPS * * *'' (69 FR 49097). Similarly, our proposal to exclude inpatient hospice days stemmed from the fact that these days are not acute care services generally payable under the IPPS.

We noted in the proposed rule that, on rare occasions, patients receiving care under a third payment category, routine home care, may also receive services in an inpatient hospital setting. Unlike inpatient respite care or general inpatient services, routine home care services are not intended to be provided in a hospital setting. For the same reasons stated above, such days should also be excluded from the Medicare and Medicaid fractions of the DPP.

We also proposed to exclude from the hospital's bed count days associated with hospice patients who receive inpatient hospice services in the hospital for purposes of both the IME payment adjustment and the DSH payment adjustment. The rules for counting hospital beds for the purposes of the IME adjustment are codified in the IME regulations at § 412.105(b), which is cross-referenced in § 412.106(a)(1)(i) for purposes of the DSH payment adjustment. Our bed counting policy is to include bed days available for IPPS-level acute care hospital services. Inpatient hospice services provided in an acute unit or ward are occasional, alternative uses of acute inpatient beds that would otherwise be considered available for IPPS-level acute care hospital services (as long as other criteria for a bed to be considered as an available bed are met under § 412.105(b)). A bed used for inpatient hospice services on a given day is not available to be used for IPPS-level services. Therefore, we proposed to revise § 412.105(b)(4) to state that such hospice days are excluded from the counts of available beds for purposes of the IME payment adjustment. Because the same rules govern the counting of available beds for purposes of the DSH payment adjustment under § 412.106(a)(1)(i), under the proposal, hospice days would also be excluded from the count of available beds for purposes of the DSH payment adjustment.

In the proposed rule, we noted that there is a circumstance in which a hospital will provide IPPS-level acute care hospital services to a hospice patient for which it would receive payment under the IPPS. This occurs when a Medicare beneficiary receiving hospice care under his or her hospice benefit requires acute care hospital services to treat a condition unrelated to his or her hospice plan of care. For example, an individual who has elected the hospice benefit could be treated in the inpatient hospital setting for a condition or illness, such as a broken bone, that is unrelated to his or her terminal illness. Under these circumstances, the patient is receiving acute care hospital services of the sort payable under the IPPS. As such, consistent with § 412.106(a)(1)(ii), we did not propose to exclude these patient

days from the Medicare and Medicaid fractions of the DPP or from the count of available beds under § 412.105(b)(4) and § 412.106(a)(1)(i).

We further noted that hospitals may have hospice units that are separate and distinct from their acute care inpatient units. Under existing regulations at § 412.105(b)(3) and § 412.106(a)(1)(ii)(A), services provided in distinct nonacute care inpatient units are excluded from the patient day and bed day count. Our proposal with respect to inpatient hospice services did not change or affect this policy.

Comment: Several commenters believed that the proposal would have an immaterial impact on providers' DSH payment adjustments while creating an unnecessary administrative burden to the extent that providers would have to take steps to identify the excluded days. The commenters requested that CMS reevaluate the administrative burden created by the need to identify hospice days in light of what the commenters describe as the immaterial impact of hospice days on the DSH payment adjustments.

Response: We do not agree with the commenters that our proposal would create an undue administrative burden for providers. Hospitals already identify hospice patients for the purpose of billing and payment. Because hospice patients in an inpatient setting are already being specifically identified for other purposes, we do not believe it would be an undue administrative burden for hospitals to identify and exclude these patients for purposes of the DSH payment adjustment.

Comment: Commenters requested clarification regarding the effective date of the proposal, including whether the regulation change is intended to be prospective. The commenters also questioned whether the change in policy would be reflected on the cost report.

Response: Our proposal to exclude hospice bed days from the calculation of the DSH payment adjustment is a regulation change that will be effective for cost reporting periods beginning on or after October 1, 2011. As we stated in the proposed rule, we plan to amend the cost reporting instructions to reflect our change in policy.

Comment: A few commenters requested that CMS not apply the intern-to-resident bed (IRB) ratio cap with respect to the proposed removal of hospice bed days from the calculation of the DSH payment adjustment. Instead, the commenters requested that hospitals be allowed to exclude these inpatient hospice days from their prior year's IRB ratio for purposes of applying that ratio as the cap on the hospital's current year IRB ratio.

Response: We believe the commenters are referring to a provision that was included in the Balanced Budget Act of 1997, known as the cap on the intern and resident-to-bed (IRB) ratio that is applicable to the IME payment that teaching hospitals receive under the IPPS. Under section 1886(d)(5)(B)(vi)(I) of the Act, and implemented in the regulations at § 412.105(a)(1)(i), a hospital's IRB ratio in the current cost reporting period generally cannot exceed, or is capped by, the value of the IRB ratio in the preceding cost reporting period. Therefore, if a teaching hospital's IRB ratio increases in the current cost reporting period relative to the prior cost reporting period, its receipt of an increase in IME payment as a result of that increase to the IRB ratio is delayed by 1 year. Because, effective for cost reporting periods beginning on or after October 1, 2011, certain inpatient hospice bed days are to be excluded from the count of available beds under § 412.105(b)(4), assuming there are no changes in the FTE resident count in the numerator of the IRB ratio from the cost reporting period occurring prior to October 1, 2011, a reduced bed count in the cost reporting period that begins on or after October 1, 2011, could cause an increase in the IRB ratio. However, because the prior cost reporting period's bed count would still reflect the inclusion of the inpatient hospital beds, the IRB ratio for the cost reporting period that begins on or after October 1, 2011 will be capped by the lower IRB ratio from the preceding period, thereby limiting the IME payment somewhat for the cost reporting period that begins on or after October 1, 2011.

We do not agree with the commenters' request to not apply the IRB ratio cap with respect to inpatient hospice days by permitting teaching hospitals to exclude the inpatient hospice days from the denominator of the IRB ratio of the prior period. While it is true that the law and regulations permit teaching hospitals to make adjustments to their prior year IRB ratios under certain circumstances such as for Medicare GME affiliation agreements, new programs, or absorption of residents displaced by another hospital's closure, we do not believe a similar exception is warranted under this policy. In this instance, no harm is occurring to either the teaching hospital or residents in the GME programs as a result of not including the bed days of hospice inpatients in the denominator of the IRB ratio. Rather, it is simply a matter of receiving an increased IME payment immediately in the current cost reporting period, or, through application of the IRB ratio cap, on a 1-year delay in the following cost reporting period. In fact, the intent of the IRB ratio cap is to modulate such changes in a hospital's IRB ratio from year to year. Therefore, we are not waiving the IRB ratio cap effective for cost reporting periods that begin on or after October 1, 2011.

Comment: One commenter requested that CMS begin implementation of the Affordable Care Act amendments to the DSH payment adjustment provisions of the Act through this rulemaking.

Response: We believe that this comment is outside of the scope of the proposed rule. The referenced statutory changes made by the Affordable Care Act do not go into effect in FY 2012 and were not addressed in this year's proposed rule.

After consideration of the public comments we received, we are adopting our proposed policies without modifications. In summary, we are excluding inpatient hospice days from the patient day count under § 412.106(a)(1)(ii) (for DSH) and the bed day count under § 412.105(b) (for IME) and under § 412.106(a)(1)(i) (for DSH).

H. Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)

1. Background

Under the IPPS, separate special payment protections are provided to a Medicare-dependent, small rural hospital (MDH). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based in part on the Federal rate and in part on the MDH's hospital-specific rate. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges either in its 1987 cost reporting year or in two of its most recent three settled Medicare cost reporting years). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

Although MDHs are paid under an adjusted payment methodology, they are still IPPS hospitals paid under section 1886(d) of the Act. Like all IPPS hospitals paid under section 1886(d) of the Act, MDHs are paid for their discharges based on the DRG weights calculated under section 1886(d)(4) of the Act.